

# **TAB 19**

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
AT CHARLESTON

_____	x	
	:	
THE CITY OF HUNTINGTON,	:	Civil Action
	:	
Plaintiff,	:	No. 3:17-cv-01362
	:	
v.	:	
	:	
AMERISOURCEBERGEN DRUG	:	
CORPORATION, et al.,	:	
	:	
Defendants.	:	

_____	x	
	:	
CABELL COUNTY COMMISSION,	:	Civil Action
	:	
Plaintiff,	:	No. 3:17-cv-01665
	:	
v.	:	
	:	
AMERISOURCEBERGEN DRUG	:	
CORPORATION, et al.,	:	
	:	
Defendants.	:	

BENCH TRIAL - VOLUME 34  
BEFORE THE HONORABLE DAVID A. FABER, SENIOR STATUS JUDGE  
UNITED STATES DISTRICT COURT  
IN CHARLESTON, WEST VIRGINIA

JULY 2, 2021

1       **A.**     Not -- not that comes to mind immediately, no.

2       **Q.**     And then, real quick, you mentioned the Chair of Pain  
3     Medicine. In part of your administrative role or your  
4     oversight of physicians, do you monitor the prescribing  
5     practices of those doctors?

6       **A.**     Yes, I do.

7               MR. FARRELL: No objection and no further  
8     questions.

9               THE COURT: The Court finds that Dr. Gilligan is  
10    an expert in the field of pain management and the risks and  
11    benefits of prescription opioids.

12              Just curious, what was your Cambridge college?

13              THE WITNESS: Jesus.

14              THE COURT: Okay.

15              BY MR. SCHMIDT:

16       **Q.**     So, Dr. Gilligan, I'd like to ask you about the  
17    condition of pain and then ask you about prescription  
18    opioids as a treatment for pain. Let's start with the pain  
19    first. Could you tell us just at a high level from your  
20    experience how pain impacts the patients you see and why  
21    it's important to treat pain?

22       **A.**     So, we see patients who their pain is at the level that  
23    they're coming to go see a pain specialist. And many of our  
24    patients have chronic pain conditions. And for a lot of  
25    those patients it's -- their pain is severe, so just their

1 level of suffering is severe.

2 But also very, very important is that, in many cases,  
3 they can't work or they can't work the way they want to. As  
4 I mentioned before, they can't take care of their family the  
5 way they want to. They can't participate in the community,  
6 socialize, exercise, et cetera. And so, not only do they  
7 have the suffering from the pain, but they have essentially  
8 -- we talk about their life being taken away from them by  
9 the pain and by the limitation in function from the pain.

10 So, frankly, some of these cases are -- if you're  
11 sitting in the room with a patient are very, very brutal.

12 **Q.** Have you seen over the course of your career the impact  
13 that pain directly has upon patients who suffer from it,  
14 particularly chronic pain?

15 **A.** Yes. I would say on a daily basis when we're -- where  
16 we're in clinic I see that.

17 **Q.** Are you familiar with published data on trying to  
18 quantify the costs and the number of people affected by  
19 pain, including chronic pain?

20 **A.** Yes, I am.

21 **Q.** I'd like to ask you about some of that data, if I may.  
22 I'm going to show you a document that the Court has seen  
23 before, but is not in evidence, MCWV-1170.

24 MR. SCHMIDT: May I approach, Your Honor?

25 THE COURT: Yes.

1 MR. SCHMIDT: And I apologize. I feel like I came  
2 back and the big documents came back.

3 THE COURT: We cleaned out the documents while you  
4 were gone, Mr. Schmidt.

5 MR. SCHMIDT: I know. I'm sorry.

6 BY MR. SCHMIDT:

7 Q. And so we know what we're looking at, Dr. Gilligan, if  
8 we go to the second page of this document, it's titled --  
9 and we can actually put it up on the screen.

10 MR. SCHMIDT: Can you switch that?

11 BY MR. SCHMIDT:

12 Q. It's entitled Relieving Pain in America. And then,  
13 about halfway down, it says it's from the Institute of  
14 Medicine. And if we go to the next page, the third page of  
15 the document using the numbers in the lower left corner, we  
16 can see near the bottom that it's from 2011. Are you  
17 familiar with this document from the Institute of Medicine  
18 and this report, Relieving Pain in America, from 2011?

19 A. Yes, I am.

20 Q. What is the Institute of Medicine?

21 A. So, the Institute of Medicine is a, frankly, very well  
22 regarded group of physicians who have been recognized as  
23 leaders and then they will be tasked by the government with  
24 writing reports on certain topics that are important to the  
25 health of Americans.

1 MR. SCHMIDT: On that basis, I'm going to move  
2 this into evidence as a public report, but if there's an  
3 objection, I can lay a little more foundation.

4 THE COURT: Is there any objection?

5 MR. FARRELL: No, Your Honor.

6 THE COURT: It's admitted.

7 MR. SCHMIDT: Okay. Thank you for that.

8 BY MR. SCHMIDT:

9 Q. Just in terms of this specific report, do you have an  
10 understanding of how this report came to be?

11 A. Well, I think it was the government recognizing that  
12 this is a topic that was very important to the health of  
13 Americans and a need for data on the scope of the problem,  
14 the state of treatments, et cetera, what were the unmet  
15 needs in the areas that needed more research and they  
16 brought together a group of experts in the field, as well as  
17 patient representatives or others.

18 Q. All right. Let's look at Page 38 of this report, if we  
19 could. And, again, I'm going to be using the numbers in the  
20 bottom left corner, which differ from the numbers in the  
21 actual document. And we have it up on the screen. I'm  
22 going to read to you the last paragraph that carries over  
23 onto Page 39 and ask you to comment on it.

24 It says pain is a universal experience but unique to  
25 each individual. Is that something you see in your medical

1 practice?

2 **A.** Yes, it is.

3 **Q.** It then says across the lifespan, pain - acute and  
4 chronic - and let me just pause right there. We're well  
5 into this trial. I don't know if we've ever defined for the  
6 Court what acute and chronic is from a pain management  
7 doctor. Can you tell us what the difference between acute  
8 and chronic pain is?

9 **A.** Sure. So, a couple of things. One is the time frame.  
10 We typically talk about pain that's acute lasting 6 or 12  
11 weeks; if pain is chronic, being longer than that, certainly  
12 longer than 12 weeks.

13 There's also a distinction because acute pain is most  
14 commonly associated something such as an injury. Someone  
15 breaks their arm, there's actually a helpful signal in that.  
16 If I -- if I break my arm and it hurts, it's telling me not  
17 to move it, and there's some value in that.

18 Chronic pain is, almost by definition, more than  
19 12 weeks and often is not, at that point, serving a useful  
20 function. So, if I break my arm and twelve weeks later it's  
21 been set, but it's still hurting severely, that's actually  
22 not giving useful information, but there's suffering and  
23 there's loss of function.

24 **Q.** So, to go back to the start of the sentence, it says  
25 across the lifespan pain, acute and chronic, is one of the

1 most frequent reasons for physician visits, among the most  
2 common reasons for taking medications, and a major cause of  
3 work disability.

4 Have you seen all three of those things in your  
5 practice in terms of pain as one of the most frequent  
6 reasons people see doctors, one of the most frequent reasons  
7 they take medicine, and one of the major causes of not being  
8 able to work?

9 **A.** Yes. I have seen all three of those.

10 **Q.** All right. Let's jump ahead, if we could, to Page 47,  
11 please. And there's a box there if we make it a little  
12 larger that says pain by the numbers. And I want to just  
13 walk through a couple pieces of data reported in this  
14 report. The first piece of data reported says 100 million,  
15 approximate number of U. S. adults with common chronic pain  
16 conditions. Do you see that?

17 **A.** I do.

18 **Q.** Have you seen similar estimates of the number of  
19 Americans who have chronic pain conditions?

20 **A.** Yes, I have.

21 **Q.** And I just want to differentiate between types of  
22 chronic pain conditions. Is cancer pain a chronic pain  
23 condition?

24 **A.** Cancer pain can also be a chronic pain condition. We  
25 talk about chronic pain related to cancer and then chronic

1 non-cancer pain is one of the ways that we divide things.

2 **Q.** In terms of chronic cancer pain, can you characterize  
3 that at all for the Court? Describe that pain.

4 **A.** So, chronic cancer pain, we do think of as a distinct  
5 topic. In many instances, somebody may have advanced cancer  
6 and they're going to have -- many of those patients will  
7 have severe pain, but they also may have -- they,  
8 unfortunately, have a limited life expectancy, frankly. For  
9 those patients opioids are typically going to be really one  
10 of the foundations of how we're going to treat the pain.  
11 For most of those patients, opioids will play a central role  
12 in how we're going to treat that pain.

13 **Q.** And you mentioned non-cancer chronic pain. Could you  
14 tell us some of the conditions that cause non-cancer chronic  
15 pain and characterize the relative severity of those?

16 **A.** So, for non-cancer chronic pain things like severe  
17 low-back pain or neck pain, severe hip or knee pain  
18 associated with arthritis and, actually, a whole host of  
19 things. Some of the autoimmune conditions, rheumatoid  
20 arthritis, Crohn's disease, et cetera. Chronic migraines.  
21 And the list would go on.

22 **Q.** Okay. Just rounding out the questions that I was  
23 asking you about this number, this is 2011, 100 million.  
24 From your experience, has this number of adults in the U. S.  
25 with common chronic pain conditions increased over time or

1 decreased over time?

2 **A.** I think that it's increased over time due to a few  
3 things. One, the population has grown. It's gotten so much  
4 older. Our population has gotten somewhat heavier and  
5 weight is associated with knee and hip arthritis, et cetera.  
6 So, I think that, overall, it has grown somewhat.

7 **Q.** Let's go to the next line and this is actually the  
8 statistic we heard about with another expert, 560 to 635  
9 billion conservative estimate of the annual cost of chronic  
10 pain in America. Are you familiar -- have you seen  
11 estimates like that in the literature in terms of trying to  
12 estimate the economic consequences of chronic pain just on a  
13 yearly basis?

14 **A.** Yes, I have.

15 **Q.** And are they consistent with this number which is north  
16 of a half trillion?

17 **A.** Yes.

18 **Q.** If we then look at the -- let's skip the next bullet  
19 which talks about state and federal government expenditures.  
20 There's a number of percentages that run down here talking  
21 about different pain conditions. Could you just walk  
22 through the numbers there that you think are meaningful for  
23 us to hear about?

24 **A.** Sure. So, I would look at the fourth bullet point for  
25 women after having a baby and look for -- at that

1 percentage. 10 percent have persistent pain at one year. I  
2 think that's significant.

3 I think, for the next bullet point, the patients who  
4 have undergone surgery, specifically, the third dash there,  
5 that 2 to 10 percent of these patients have chronic  
6 postoperative pain that's severe. And what's important  
7 there is that it's chronic. That's not right after surgery.  
8 That's after they would have been expected to heal up, so to  
9 speak.

10 I think the bullet point just below that, 5 percent of  
11 the portion of American women 18 to 65 who have headache 15  
12 or more days per month, I think that's quite significant.

13 And I think the second to last bullet point, the  
14 percentage per U. S. nursing home residents, I would look at  
15 the second dash there, that 17 percent have substantial  
16 daily pain.

17 **Q.** A few more questions about this document.

18 MR. SCHMIDT: Could we go up to Page 162, please?

19 BY MR. SCHMIDT:

20 **Q.** And if we look here, there's a paragraph -- there's a  
21 sub-header that says Patient Access to Opioids. Do you see  
22 that?

23 **A.** I do.

24 **Q.** And it states in this 2011 Institute of Medicine  
25 publication a reasonable degree of access to pain medication

1 - such as the stepped approach of the World Health  
2 Organization's pain relief ladder for cancer - has been  
3 considered a human right under international law since the  
4 1961 adoption of the U. N. Single Convention on Narcotic  
5 Drugs. Do you see that?

6 **A.** I do.

7 **Q.** And is that -- is that consistent with your perspective  
8 in terms of how the medical field views having prescription  
9 opioids for appropriate cases?

10 **A.** It -- yes, it is.

11 **Q.** And then, if we go to the next paragraph, please, it  
12 says in the United States, many pain experts agree that  
13 physicians should prescribe opioids when necessary  
14 regardless of outside pressure as an exercise of their moral  
15 and ethical obligations to treat pain. Do you see that?

16 **A.** I do.

17 **Q.** Is that something you see within the course of your  
18 career, that view among many physicians, that you should  
19 prescribe prescription opioids where appropriate when  
20 necessary as part of a moral and ethical obligation to their  
21 patients?

22 **A.** Yes, it is.

23 **Q.** All right. Let's shift gears a little bit. I want to  
24 now talk about treatments for pain and I'm going to touch on  
25 prescription opioids in a minute, but before I do, I want to

1 talk about nonprescription opioid treatments for pain. Are  
2 there treatments for pain that don't involve any kind of  
3 medicine?

4 **A.** Yes, there are. Examples would be physical therapy.  
5 Not involving medicine would include different  
6 interventions, things like acupuncture, chiropractic  
7 manipulation. There's some psychological treatments, things  
8 such as teaching patients relaxation techniques, biofeedback  
9 et cetera. So, short answer, there are.

10 **Q.** Do those types of treatments have limitations in terms  
11 of addressing pain?

12 **A.** They do. There are some patients who are very much  
13 benefited by them and, frankly, with those patients one  
14 would likely be stopping there. And then there are other  
15 patients who you try each and every one of those that seems  
16 appropriate for their case and, unfortunately, it doesn't  
17 work. It doesn't give them relief. It doesn't return their  
18 function.

19 **Q.** When it comes to prescription medicines or just  
20 medicines generally, before I turn to opioids, are there  
21 other kinds of medicines that can be used to treat pain  
22 other than prescription opioids?

23 **A.** Yes, there are. We use common anti-inflammatory  
24 medications, Advil, Motrin, Aleve, things in that class.  
25 So, nonsteroidal anti-inflammatories. We use muscle

1 relaxants.

2 There are groups of medications that are not opioids  
3 that we use specifically to treat nerve pain. Those are  
4 medications such as Neurontin. So, by trade name,  
5 Neurontin, and Lyrica, and Cymbalta.

6 And then there's a whole host that are topical things  
7 we have patients put on -- on the -- the Lidocaine patch,  
8 for example.

9 **Q.** Are there limitations to those kinds of treatments?

10 **A.** Yes. Similar to what we just talked about, there are  
11 some patients who get excellent relief from them and,  
12 perhaps in many of those cases, one would stop there again.

13 There are other patients who don't get relief or can't  
14 tolerate side effects. And then there are some patients  
15 where there's a risk so you can't use those medications,  
16 where it would be too dangerous to use those medications  
17 given that person's specific medical history, accompanying  
18 conditions, other medications they take.

19 **Q.** And I want to just pick up on an idea you alluded to.  
20 You mentioned risks for some patients for those medications'  
21 side effects. Do those medications carry their own distinct  
22 risks that you have to take into account when deciding  
23 whether to use them?

24 **A.** Yes. Those medications have their own risks that you  
25 have to take into account and, frankly, essentially every

1 medication that a doctor prescribes has risks and benefits  
2 and the job is to look at the individual patient in front of  
3 you, take into account all of the information you have  
4 available, weigh the risks and benefits of essentially any  
5 medication that you're going to prescribe for that patient.

6 **Q.** Okay. So, I want to -- I want to turn from those  
7 nonprescription opioid treatments to prescription opioids  
8 and pick up on that concept that you were just talking about  
9 in terms of benefits and risks and weighing those. In your  
10 opinion, are there patients for whom the benefits of  
11 prescription opioids outweigh the risks?

12 **A.** Yes, there are.

13 **Q.** And can you talk about why that is?

14 **A.** So, when we're weighing the risks and benefits of  
15 opioid medications, a few things. One, we can get some  
16 information about how high risk a given patient is for  
17 developing addiction. If someone is at high risk for  
18 developing addiction, they have a history of substance  
19 abuse, they have a history of major untreated psychiatric  
20 conditions such as bipolar, strong family history of  
21 substance abuse, et cetera, would be at higher risk of  
22 addiction.

23 There are other folks who we can identify as being very  
24 low risk and there are other factors that come into it,  
25 which is what's the patient's condition, the severity of it,

1 to what extent can non-opioid treatments get that patient  
2 pain relief and return to function, and then to what extent  
3 are those safe for that given patient. So, there's a whole  
4 host of things that come into that risk benefit.

5 **Q.** That view you just expressed to us about the benefits  
6 outweighing the risks for certain patients, do you  
7 understand that to be the consensus of the medical community  
8 when it comes to prescription opioids?

9 **A.** Yes, I do.

10 **Q.** Do you have an understanding as to whether that  
11 consensus is reflected in the fact of FDA approval of  
12 prescription medicines?

13 **A.** Yes. I think that the FDA approval of those  
14 medications reflects a consensus that for certain patients,  
15 for selected patients' judicious use, the benefits outweigh  
16 the risks.

17 **Q.** I would like to talk a little bit more about, first,  
18 the risks of prescription opioids and then some of the  
19 benefits. And to do that I want to use as an illustration  
20 point something referred to as a label for a prescription  
21 medicine or the prescribing information. Are you familiar  
22 with that document for different prescription medicines, the  
23 label, or the prescribing information?

24 **A.** Yes, I am. We also call it the package insert  
25 sometimes.

1 MR. SCHMIDT: May I approach, Your Honor?

2 THE COURT: Yes.

3 BY MR. SCHMIDT:

4 Q. Doctor, I've handed you what we've marked as MCWV-1197,  
5 which is a label for prescription medicine, and I will  
6 apologize to all concerned in advance. We seem to have  
7 found the smallest print copy possible of this document.  
8 Fortunately, Mr. Reynolds can blow it up on the screen for  
9 us.

10 If we could start in the upper left corner just to make  
11 it large, it says Percocet (oxycodone and acetaminophen  
12 tablets) C-II, controlled substance II, Schedule II,  
13 prescription only. Do you see that?

14 A. I do.

15 Q. Are you familiar with -- from your work with this label  
16 for Percocet, a prescription opioid?

17 A. Yes, I am.

18 Q. And just before we look a little bit at the contents of  
19 this, what do you understand to be the purpose of a document  
20 like this, the label, and who do you understand it to be  
21 written for?

22 A. So, my understanding is that the purpose of the label  
23 is in part for clinicians to tell them what's the  
24 indication, which of the medications be -- what is it  
25 indicated for, what's -- what are some of the risks of the

1 medication, something about the pharmacology, the contents  
2 of the medication.

3 Specific things. You know, what you should do if the  
4 patient has, for example, reduced kidney function with that  
5 medication or interactions with other medications.

6 And then there's also some information that's directed  
7 to patients and to their families in this.

8 **Q.** This version of the label has -- it says right below  
9 the title we were looking at, it says revised July, 2018.  
10 Do you see that?

11 **A.** I do.

12 **Q.** Do you have an understanding as to whether the label  
13 for a given medicine is regularly and periodically updated  
14 over time as new information becomes available?

15 **A.** My understanding is that they are, yes.

16 **Q.** And I want to pick up on something you were telling us  
17 about in terms of some of the information. If we look at  
18 this label, we see here there's a black box warning. And  
19 then, if we scroll down below that past the black box  
20 warning, please, it looks like there are different sections,  
21 including some of the ones you mentioned.

22 We see something called the description of the  
23 medication. Then, if we go to the next column, we see  
24 pharmacokinetics, metabolism and elimination, something you  
25 mentioned, indications and usage, contraindications,

1 warnings, et cetera.

2 And before diving into just a few of those sections, do  
3 you have an understanding that what we're seeing here is  
4 written according to a specified format in terms of these  
5 different sections and what's supposed to appear, the types  
6 of information that are supposed to appear in those  
7 different sections?

8 MR. FARRELL: Objection, Your Honor. I'm not  
9 quite sure that the doctor has been identified as an expert  
10 in labeling.

11 MR. SCHMIDT: I think it's something he deals with  
12 every day. If it's necessary, I can lay more of a  
13 foundation but --

14 THE COURT: It seems to me that the labeling is  
15 well within his field of expertise that I qualified him in.  
16 So, I'm going to overrule the objection.

17 MR. FARRELL: Just to preserve for the record, I  
18 don't have any problem with him testifying what's in the  
19 label. What I have an objection to is I believe the  
20 question of -- is what is his understanding of what the FDA  
21 requires to be in the label.

22 BY MR. SCHMIDT:

23 Q. So --

24 THE COURT: I'm going to allow it. Overruled.

25 BY MR. SCHMIDT:

1 Q. Dr. Gilligan, from -- I'm not going to ask you -- we  
2 haven't asked you to come here as an FDA expert, have we?

3 A. You have not, no.

4 Q. I'm going to ask you just some questions about this  
5 label from your perspective as a physician. As a physician,  
6 do you have occasion to consult with labels for a range of  
7 different medicines and gather information from them?

8 A. Yes, I do.

9 Q. Does that require you to have basic information about  
10 how they're formatted, at a high level, what goes into them?

11 A. Yes, it does.

12 Q. And so, when you look at different labels, do you see  
13 that they have a specified format across different  
14 medications with some of these sections we've been talking  
15 about, warnings, indications, contraindications, and  
16 specified information in those sections?

17 A. Yes. This is the typical type content and layout.

18 Q. And you heard reference to the FDA. Do you know  
19 whether these labels are FDA approved?

20 A. Yes, they are.

21 Q. Is that relevant to you in your medical practice?

22 A. It's relevant to us because the information is useful  
23 when you're prescribing these, you know, for all of the type  
24 of topics that we've talked about. It informs your decision  
25 to prescribe or not, and how to prescribe, what dose to

1 prescribe, et cetera, and it's -- it is important to us that  
2 this language has been approved by FDA in terms of feeling  
3 comfortable relying on it.

4 **Q.** Do you have the understanding that the companies that  
5 manufacture these medicines are responsible for the contents  
6 of these labels?

7 **A.** Yes. My understanding is that -- and my experience,  
8 actually, is that there's a discussion between the company  
9 and the FDA about what will be -- what will be agreed to go  
10 into the label.

11 **Q.** And from your experience when this label sets forth the  
12 -- well, let me just ask you a question. Without getting  
13 into the substance here, what do you understand the  
14 indications to tell you as a doctor?

15 **A.** So, it tells you what condition FDA has approved the  
16 medication for use for.

17 **Q.** And then, obviously, what do you understand the  
18 warnings to tell you?

19 **A.** That they want to make it quite clear to you what the  
20 potential risks of the medication in question is, what the  
21 medication -- what the specific identified risks of  
22 whichever medication it may be are so that you know them and  
23 can put them into that risk benefit balance that we talked  
24 about.

25 **Q.** In terms of determining the substance of what this

1 label says, including who the medication might be  
2 appropriate for, what the warnings that doctors need to  
3 understand are, from your experience, do you know of any  
4 role that wholesale distributors play in this content?

5 **A.** No. My understanding is they play no role in that.

6 **Q.** All right. So, let's look at the specific language.  
7 And if we could go back to the first page to the black box  
8 warning just to try to facilitate the structure here. It  
9 says WARNING:, colon, in all caps, and then it lists a  
10 series of conditions, addiction, abuse, and misuse.

11 And then it talks about a risk evaluation, mitigation  
12 and strategy. And it looks like those conditions then  
13 repeat with a little bit more information further down. Do  
14 you see that?

15 **A.** I do.

16 **Q.** And so, I want to start with the warning about  
17 addiction, abuse and misuse. Could you tell us what those  
18 terms mean?

19 **A.** So, addiction is when a patient develops a compulsive  
20 self-destructive craving to use -- essentially an out of  
21 control use of -- of a substance and, in this case,  
22 oxycodone. There are many substances, of course, that  
23 people can get addicted to. So, it's a compulsive, and out  
24 of control, and self-destructive use of a substance is  
25 addiction.

1 THE COURT: Just a minute.

2 Mr. Ackerman?

3 MR. ACKERMAN: Your Honor, if I may, this document  
4 is not in evidence, I don't believe, unless I missed  
5 something. And so, I have an objection to displaying it on  
6 the board.

7 MR. SCHMIDT: We'll move it into evidence, Your  
8 Honor.

9 THE COURT: Any objection to it being admitted,  
10 Mr. Ackerman?

11 MR. ACKERMAN: Hearsay.

12 MR. SCHMIDT: I think, at a minimum, it can come  
13 in for the limited purpose of effect on doctors. It's  
14 MCWV-1157.

15 THE COURT: I'll admit it for the limited purpose.

16 This is helpful to the Court and I -- I think that the  
17 limit -- it's permissible for the limited purpose.

18 Go ahead, Mr. Schmidt.

19 BY MR. SCHMIDT:

20 **Q.** I think you had told us what addiction is. Can you  
21 tell us what abuse and misuse are?

22 **A.** Sure. So, abuse and misuse, on the other hand, are  
23 just taking the medication, we'd say, for a non-medical use;  
24 in other words, taking the medication for the sake of  
25 euphoria or whatever, whatever it may be, but not taking it

1 for a medical use to get -- to get pain relief. But someone  
2 who is abusing or misusing a drug might be addicted, but  
3 they also might not be addicted. They might just be abusing  
4 and misusing it without having -- without -- being addicted.

5 **Q.** Under that heading it says Percocet exposes patients  
6 and other users to the risks of opioid addiction, abuse, and  
7 misuse, which can lead to overdose and death. Can you tell  
8 us just at a high level what that's communicating to  
9 doctors?

10 **A.** So, it's being very -- very clear to the doctors that  
11 whether a patient develop -- if patients develop an  
12 addiction or if they abuse or misuse the medication that  
13 these medications can cause an overdose and that an overdose  
14 can be deadly. And so, they are making that very starkly  
15 clear.

16 **Q.** It continues to say assess each patient's risk prior to  
17 prescribing Percocet and monitor all patients regularly for  
18 the development of these behaviors and conditions. (See  
19 warnings). Do you see that?

20 **A.** I do.

21 **Q.** Can you tell us what that's counseling doctors to do?

22 **A.** So, that's counseling doctors to do some of the things  
23 that we talked about before of -- we call it opioid risk  
24 stratification, of looking at all of the information that  
25 you have about the patient in front of you; in many cases,

1 using their validated questionnaires that can help you to do  
2 risk stratification so to make sure best informed  
3 determination, is this patient high risk, medium risk or low  
4 risk for addiction abuse and misuse if the doctor prescribes  
5 opioid pain medications.

6 **Q.** And this reference here to see warnings, let's go back,  
7 if we could, to the second column to that section we saw  
8 briefly that says warnings. Is this a reference to further  
9 information about addiction abuse and misuse?

10 **A.** Yes. It's expanding on that topic essentially.

11 **Q.** I want to go back to the black box warning, if we  
12 could, and look at one more section. If we scroll down a  
13 little bit there's also a heading on Neonatal Opioid  
14 Withdrawal Syndrome. And then it has warnings about that  
15 again with a cross-reference to the warnings section for  
16 further information. Do you see that?

17 **A.** I do.

18 **Q.** We've heard in court about a condition called NAS. Is  
19 that related to this condition?

20 **A.** Yes. It's essentially another way of saying -- saying  
21 that same thing essentially.

22 **Q.** And if we go back up to the abuse, addiction and misuse  
23 -- addiction abuse and misuse section, just to reemphasize  
24 the point, in your experience, do these types of warnings  
25 change over time and often become more developed over time?

1       **A.**    Yes.  In my experience, they do change over time and  
2       they do have a tendency to become more developed, yes.

3       **Q.**    In terms of these warnings we're focusing on now,  
4       addiction, abuse and misuse, have you always understood  
5       those to be a serious risk of opioid abuse throughout your  
6       career and your medical training?

7       **A.**    Yes, I have.

8       **Q.**    And do you understand that to be a broad understanding  
9       within the medical field?

10      **A.**    Yes, I do understand it to be a broad understanding  
11      throughout the field of medicine.

12      **Q.**    Does that knowledge of the risk of addiction, abuse,  
13      misuse impact how you prescribe opioids?

14      **A.**    Yes, very much so, because it's -- again, with opioid  
15      prescribing or all medications it boils down to largely risk  
16      versus benefit and, as a key risk, that's a very significant  
17      factor in your decision to prescribe or not and, if you do  
18      prescribe, what to prescribe, how much to prescribe, how  
19      long to prescribe, et cetera.

20      **Q.**    Can addiction be an extremely serious condition?

21      **A.**    Addiction can be a fatal condition.

22      **Q.**    Does the risk in your experience and from your  
23      understanding of the science vary across patients you might  
24      see?

25      **A.**    I'm sorry.  Can you repeat the question, please?

1       **Q.**    Yes.  I'm sorry.  Does the risk from your experience  
2       vary across the range of patients you see, the risk of  
3       addiction and abuse and misuse?

4       **A.**    Yes.  The risk of addiction, abuse and misuse varies  
5       quite significantly across patients.

6       **Q.**    And can you give us a little more information as to how  
7       that's so?

8       **A.**    Sure.  So, we talked already about that there are  
9       validated risk stratification questionnaires that you can  
10      use with patients.  There are also characteristics.  And  
11      those are some of the things we talked about of a personal  
12      history of substance abuse, a family history of substance  
13      abuse, a major psychiatric condition, such as Bipolar  
14      Disorder, ADHD.

15             There are also some just demographic factors, age,  
16      gender can play into it, so that you can -- you can say not  
17      with perfect accuracy, but with very meaningful information  
18      one patient is very at high risk.  One patient is medium  
19      risk.  And one patient is low risk.  And you can even  
20      identify somebody who might be very, very low risk.

21      **Q.**    And in your experience in your career, you've kind of  
22      touched on steps you take with your patients to try to weigh  
23      that risk and benefit on an individual patient basis.

24      Taking those steps, can you comment on how common -- how  
25      common that you've seen addiction in the patients you treat

1 with prescription opioids?

2 **A.** So, for the patients who I have initiated the opioids,  
3 I have not seen a patient who has developed addiction. I  
4 have treated patients who were referred to me by other  
5 physicians who were on opioids who have developed addiction  
6 and misuse and abuse.

7 MR. SCHMIDT: And I apologize. May I approach,  
8 Your Honor?

9 THE COURT: Yes.

10 MR. SCHMIDT: I've been sitting up here drinking.  
11 I don't know if this is your water. Oh, it is? Okay. I'll  
12 give you one more just in case.

13 THE WITNESS: Thank you.

14 BY MR. SCHMIDT:

15 **Q.** Just to go back to that last answer you gave me about  
16 how rare it is in your practice, how do you know that's true  
17 in terms of how do you know you're not seeing addiction that  
18 you just don't hear about?

19 **A.** So, that certainly could be possible, but we're the  
20 largest healthcare system in Massachusetts and we have one  
21 single computerized medical record where we can see all of  
22 the tests, all of the notes, et cetera.

23 And so -- and if a patient does develop a problem with  
24 addiction, it's highly, highly likely that over time they  
25 will have an encounter with the healthcare system related to

1 that. And since we're the biggest healthcare system in  
2 Massachusetts and have a single computer record that we see  
3 and that we monitor our patients, we see them monthly if  
4 they're on opioids, we follow urine toxicology, et cetera.  
5 We monitor them closely.

6 I think it would be extremely unlikely that one of my  
7 patients would develop addiction and that I would not be  
8 aware of it.

9 **Q.** I want to just finish up with some questions about this  
10 prescribing information, this label, and then dive into one  
11 specific aspect of abuse and misuse with you. I've been  
12 referring to this as a black box warning. Do you know what  
13 that is from your medical practice?

14 **A.** Yes. From a doctor's point of view a black box warning  
15 is -- not all medications have a black box warning and the  
16 FDA puts on the label of certain medications a black box  
17 warning when they feel there's a specific serious risk that  
18 they want doctors to be particularly aware of, so they put a  
19 black box around it.

20 We know to look for that, to take it seriously, and  
21 they typically put it, in my experience, at the front of the  
22 label, again, to emphasize it to clinicians.

23 **Q.** One more question on this label. If we go to the  
24 second to last column, or third to last column, I apologize,  
25 it says medication guide. Percocet. And then it's got an

1 explanation of what Percocet is that reads a little more  
2 common sense than the language we were looking at before.  
3 Can you tell us what a medication guide is, to your  
4 understanding, what it's intended for?

5 **A.** So, a medication guide is aimed at the patient or the  
6 patient's family members; whereas, the other portion was  
7 aimed at clinicians, doctors, et cetera, the medication  
8 guide is aimed in more -- in simpler language. So, aimed at  
9 the patient, or the patient's family members, or associates.

10 **Q.** And just focusing on these two bullets, it says  
11 Percocet is, and then, one, a strong prescription pain  
12 medicine that contains an opioid narcotic that is used to  
13 manage pain severe enough to require an opioid analgesic and  
14 for which treatments are inadequate and when other pain  
15 treatments such as non-opioid pain medicines do not treat  
16 your pain well enough or you cannot tolerate them.

17 Is that talking about where the medicine is supposed to  
18 be used?

19 **A.** That's exactly what it's doing, yes.

20 **Q.** It then says an opioid pain medicine that can put you  
21 at risk for overdose and death. Even if you take your dose  
22 correctly as prescribed, you are at risk for opioid  
23 addiction, abuse and misuse that can lead to death. Do you  
24 see that?

25 **A.** I do.

1       **Q.** And, again, just recognizing that these documents  
2 change over time, is it your understanding that that's what  
3 this medication guide now tells patients?

4       **A.** That is my understanding, yes.

5       **Q.** All right. That's what I wanted to cover with you on  
6 that document.

7               I want to switch gears a little bit and pick up on a  
8 concept that we've heard about, we've sometimes heard  
9 referred to as gateway. In your experience, are there  
10 patients you know of or individuals you know of who have  
11 misused prescription opioids at one point in time and then  
12 later misused heroin?

13       **A.** Yes, there are.

14       **Q.** Can you comment on how common that is in patients you  
15 have treated?

16       **A.** So, that's been -- that's been quite rare in patients  
17 I've treated. For example, that has not happened a single  
18 time in a patient where I -- that I'm aware of in a patient  
19 that I initiated opioids, but I have seen it happen in  
20 patients who I have been involved in the treatment where  
21 other -- other physicians had initiated the opioids.

22       **Q.** Are you aware of scientific literature that speaks to  
23 that question and tries to analyze that question?

24       **A.** Yes, I am.

25       **Q.** I want to show you one article on that as an example,

1 used heroin, who had previously misused prescription  
2 opioids, whether if you took away that prescription --  
3 misuse of prescription opioids, but still had the other  
4 factors, the 98.9 percent who are abusing illegal drugs and  
5 then the other factors you just alluded to, whether that  
6 would change the heroin rates, do you know?

7 **A.** You can't say.

8 **Q.** And why is that?

9 **A.** Because even if you took away the misuse and abuse of  
10 the prescription opioids, all of those other risk factors,  
11 there are folks who already are engaged, 98.9 percent of  
12 them, in use abuse, misuse of illicit substances. So, by  
13 definition, they're engaged in that and would be at risk of  
14 additional substance abuse, including heroin abuse and  
15 misuse.

16 **Q.** Can you say looking at this data whether this is a  
17 problem that's isolated to the misuse of prescription  
18 opioids, as opposed to a broader substance abuse problem?

19 **A.** So, it's a broader substance abuse problem where, in  
20 some patients or in some individual's case there is misuse  
21 and abuse of prescription opioids, but it's a broader  
22 substance abuse problem.

23 **Q.** Let's conclude with that topic. I want to go back to  
24 what we were talking about in terms of benefit and risk.  
25 We've spent a lot of time talking about risk, pretty serious

1 risk. Given those risks of prescription opioids, why is it  
2 that doctors still use prescription opioids?

3 **A.** So, the reason that doctors still use prescription  
4 opioids despite those risks that we've talked about, which  
5 are significant, is that they're our most potent pain  
6 medications and there are some cases where patients have  
7 severe disabling pain that we can't treat successfully  
8 and/or safely with non-opioid treatments.

9 And so, there's some patients where it clearly does add  
10 up in terms of risk benefit to treat them with the opioids  
11 and, as we talked about before, there's some patients where  
12 those risks we can identify as being substantially lower for  
13 that patient. So, in the end, that risk benefit does fall  
14 squarely on using opioids to treat that patient's case.

15 **Q.** You talked earlier about your clinical research, your  
16 scientific research. Have there been efforts in the  
17 scientific community over time to come up with alternatives  
18 to prescription opioids that would be as effective at  
19 treating pain without having these risks we've been talking  
20 about?

21 **A.** Yes. Identifying a very powerful non-opioid pain  
22 medication that's safe and has no risk of addiction has  
23 essentially been a holy grail of our field.

24 **Q.** Have pain management found that holy grail?

25 **A.** Not -- not yet.

1       **Q.**     Okay. Let me talk about data for a little bit on  
2       prescription opioids. Are you familiar --

3               THE COURT: Is this a good place to stop? It's  
4       about break time, Mr. Schmidt.

5               MR. SCHMIDT: Sure. Yeah. Yeah.

6               THE COURT: Let's be in recess for about ten  
7       minutes.

8               You can step down, Dr. Gilligan.

9               THE WITNESS: Thank you, Your Honor.

10              (Recess taken)

11              (Proceedings resumed at 10:37 as follows:)

12              THE COURT: When you're ready, Mr. Schmidt.

13              MR. SCHMIDT: Thank you, Your Honor.

14       BY MR. SCHMIDT:

15       **Q.**     Dr. Gilligan, I want to pick up with where we were  
16       by talking about the benefits of these medicines.

17              You talked a little bit about the search for  
18       alternatives. And I wanted to talk to you a little bit  
19       about, in broad terms your understanding of the data  
20       regarding these medicines.

21              Are you aware of studies showing that opioids are  
22       effective for treating acute pain?

23       **A.**     Yes, I am.

24       **Q.**     And what -- can you speak to what the data shows in  
25       terms of using prescription opioids to treat chronic pain?

1     **A.**     So for chronic pain, the data with chronic opioid  
2     therapy is, frankly, more mixed. There are studies that  
3     show that if you use chronic opioid therapy for non-cancer  
4     pain cross a population in the study, in some studies that  
5     you don't see an improvement in function, or even a subset  
6     is you don't see an improvement in pain. Some show  
7     improvement. Some don't. And the studies show high rates  
8     of harm, of adverse effects from chronic opioid therapy for  
9     non-cancer pain.

10    **Q.**     So does that mean that doctors today never use  
11    prescription opioids for chronic non-cancer pain?

12    **A.**     No, it does not.

13    **Q.**     So can you explain that -- can you reconcile that for  
14    us? Why are doctors using it if the study data is mixed?

15    **A.**     So if the study data is showing across a population in  
16    a study you're not seeing an improvement in function, in  
17    some cases in pain in many of those studies, but there are  
18    certain individual patients who do do very well.

19            So it's the difference between an individual patient if  
20    you select someone who has low risk for developing problems  
21    with addiction who has a condition that you're being very  
22    selective, the indication for using it for that condition is  
23    really quite strong and the benefit, or the potential  
24    benefit for that patient is quite high. It's the difference  
25    between there are some individual patients who do very well

1 versus what you see when you look at a population in a study  
2 on average.

3 **Q.** Do you understand that view you just expressed that  
4 there are individual patients for whom prescription opioids  
5 are appropriate for chronic non-cancer pain, do you  
6 understand that view to be the consensus of the medical  
7 community?

8 **A.** Yes, I do.

9 **Q.** For example, are you familiar with CDC guidelines that  
10 have come out in the last several years regarding the use of  
11 prescription opioids in chronic non-cancer pain?

12 **A.** Yes, I am.

13 **Q.** And do they allow for or recognize that for some  
14 patients using prescription opioids for chronic non-cancer  
15 pain is appropriate?

16 **A.** They do. They spell out what are the circumstances  
17 where it would be appropriate to do it. They spell out how  
18 to do it judiciously and cautiously. They spell out  
19 guidance on what types of doses to use, et cetera, how to  
20 monitor patients.

21 But the whole point of those guidelines implicit in  
22 them is that they are giving you guidance on when and how to  
23 appropriately use opioid pain medications for chronic  
24 non-cancer pain.

25 **Q.** Dr. Gilligan, there's been discussion in the case

1 about -- a little bit of discussion in the case about  
2 prescribing levels of opioids in the United States versus  
3 other countries.

4 Do you have experience in your medical practice with  
5 use of prescription opioids in countries where they're much  
6 more restricted and conservative in using prescription  
7 opioids?

8 **A.** I do.

9 **Q.** Can you tell us about that experience?

10 **A.** Sure. So in one of my roles at the Brigham is that I'm  
11 the Medical Director for an affiliation that we have with a  
12 cancer hospital in China. And in China, the use of opioids  
13 for cancer pain and for non-cancer pain is far, far more  
14 conservative than it is in the United States.

15 **Q.** And how do you see that play out in your experience in  
16 terms of patient care?

17 **A.** So there are some patients who we see there who --  
18 their pain is -- could be safely and much more effectively  
19 controlled if opioids were used in their cases and in the  
20 way that we would use it; in other words, cautiously  
21 judiciously but appropriately.

22 We see some patients who in our judgment are, for  
23 example, dying of cancer and suffering from very, very  
24 severe pain that we think could be more effectively and  
25 safely treated with opioids.

1       **Q.**    We've been talking about the risks and benefits of  
2       opioid medications. Do you have a view as to who in the  
3       healthcare system is best situated to counsel patients on  
4       those benefits, on those risks?

5       **A.**    I do.

6       **Q.**    Who is that?

7       **A.**    I think clinicians, principally doctors, because our  
8       education is to have abundant knowledge about the conditions  
9       and the medications and their risks and the potential  
10      benefits.

11           Our training is training us to make those judgments,  
12      how to take in that information and take it in, weigh in,  
13      you know, what's high quality information, what's low  
14      quality information that you should tend to discount, et  
15      cetera.

16           And then for these controlled substance prescription  
17      medications, that's the, the authority that we get when we  
18      get DEA certification, medical license, controlled substance  
19      certificate, et cetera, that is both giving us that  
20      authority to make a prescribing decision.

21           And the accompanying oversight bodies in our field are  
22      also there for in case a physician stops prescribing  
23      appropriately. And that can be at the level of the  
24      hospital, at the Board of Registration of Medicine, could be  
25      the DEA pulling somebody's certificate, et cetera.

1           So everything about our education, training, role,  
2           authority, and then responsibility and monitoring is, is  
3           matched to our role in making those decisions.

4           **Q.**    I want to pull out some of those points you just walked  
5           us through in a little more detail if I could.

6                    Let me start with, with the first part of what you said  
7           for us. In terms of access to medical records, access to  
8           the patient, is, is there anyone or entity in the healthcare  
9           system that has more visibility to the patient than the  
10          doctor or other clinicians who's treating them?

11          **A.**    No, there isn't because we're the one who's in the exam  
12          room. We're taking the patient's complete relevant medical  
13          history and demographic history, et cetera. We're examining  
14          the patient. We're looking at the results of any relevant  
15          test, X-rays, MRIs, lab tests, et cetera. The other -- at  
16          least I can't think of another party that has that level of  
17          information specific to that patient.

18          **Q.**    Uh-huh.

19          **A.**    And these decisions are all about the individual  
20          details of that individual patient's case. That's the  
21          essence of, of making those decisions appropriately and  
22          correctly in individual cases.

23          **Q.**    As a physician, are you bound by both legal  
24          responsibilities regarding your patient and ethical  
25          responsibilities?

1       **A.**    Yes, we are.

2       **Q.**    And do you have a view whether it would further those  
3       legal and ethical responsibilities if you were caring for  
4       your patients and making judgments for your patients other  
5       participants in the healthcare system like distributors were  
6       second-guessing those judgments?

7       **A.**    I, I don't think that that would be helpful for our  
8       patients. I don't think that would be helpful for society.  
9       I do not think that that would help to make the decisions be  
10      done more appropriately.

11      **Q.**    You, you talked about some consequences in your answer  
12      a few moments ago for doctors who don't practice within  
13      those standards. You were talking about including losing  
14      their ability to practice, maybe going to jail. And we've  
15      heard some examples of that.

16             But short of losing a license or criminal action, are  
17      there other controls in your experience that apply to  
18      doctors who are inappropriately prescribing?

19      **A.**    Yes, there are.

20      **Q.**    Can you tell us about some of those?

21      **A.**    So when we have concerns within our healthcare system  
22      about a physician's prescribing, we'll step in and we'll  
23      monitor that physician's prescribing. We will, for example,  
24      pull 25 charts per month from that patient, that physician's  
25      patients and review those records and look at the records

1 and say were the prescribing decisions in each of those  
2 cases made appropriately or not.

3 We'll do didactic education sessions sometimes one on  
4 one with that physician and other things along those lines.

5 **Q.** And you just in giving that answer referred to yourself  
6 in the first person plural. Have you been involved in that  
7 kind of review of other physicians' prescribing practices so  
8 you can make judgments about whether it's appropriate or  
9 inappropriate?

10 **A.** Yes, I have.

11 **Q.** Is that something you're able to do just by looking at  
12 prescribing records and prescribing levels or, or do you  
13 need more patient information?

14 **A.** When I do that and when we do that in general, we need  
15 the patient level information because you can't determine if  
16 a given prescribing decision was appropriate or not unless  
17 you get the relevant information; in other words, what was  
18 the patient's history, what were the findings on exam, what  
19 did the tests show, what other therapies were tried, et  
20 cetera, to make that determination about that case.

21 **Q.** Okay. Does making that determination require you to  
22 exercise medical judgment based on your medical training?

23 **A.** Yes, it does.

24 **Q.** I'm going to turn to our last topic. It's a larger  
25 topic. It might take us close to lunch or just shy of

1 lunch. And it's, it's a concept that we've heard referred  
2 to as standard of care. Is that a concept you're familiar  
3 with in medical practice?

4 **A.** Yes, it is.

5 **Q.** Can you tell us what that means in terms of medical  
6 practice?

7 **A.** So standard of care in medical practice means the  
8 quality of care, the thoroughness, the safety of care that  
9 doctors expect to maintain in his or her fields. Sometimes  
10 there's a geographic component to it, you know, in  
11 practicing in your field and in the area where you practice,  
12 what you would be expected to do. And that can apply to  
13 anything. That can apply to the -- what you should be  
14 expected to have done if somebody came in with a potential  
15 heart attack.

16 **Q.** I want to focus on prescription opioids. Are you aware  
17 of whether the standard of care regarding prescription  
18 opioids has changed over the past several decades?

19 **A.** Yes, it has.

20 **Q.** And at a high level can you walk us through that  
21 change?

22 **A.** So in the period around the 1990s in particular, a  
23 little bit in there, 1980s as well, there was an emphasis on  
24 the concept that we were under-treating pain in this country  
25 and that we were placing too much emphasis -- that we were

1 exaggerating, would have been the argument, the potential  
2 risks of opioids, that we were under-utilizing them and we  
3 were leaving too many patients with pain that could have  
4 slash should have been treated with opioids.

5 Then as prescribing went up by about certainly I think  
6 roughly the mid 2000s, there was much more awareness of the  
7 adverse effects and the argument that perhaps we were  
8 prescribing too many opioids as opposed to too few, and that  
9 we were -- that we should put more emphasis on the potential  
10 risks of the medication.

11 Then around 2011 prescribing in the country peaked and  
12 started to go down. And since then, there's been  
13 significant emphasis on the, the risks of these medications,  
14 potential risks, the fact that there are some patients with  
15 chronic non-cancer pain, for example, who don't get  
16 significant benefit where -- while there are some people who  
17 do.

18 And, so, an emphasis on still using the medications but  
19 being more conservative about them as part of the standard  
20 of care.

21 **Q.** Okay. We, we've heard evidence in this case about  
22 prescribing rates in Cabell County, West Virginia. And I  
23 want to just ask you if that's consistent with what you just  
24 told us.

25 The evidence is prescribing rates increased in the late

1 '90s up until a peak in about, between 2010, 2012, that  
2 range, and then have gone back down. Is that consistent  
3 with those changes in the standard of care that you told us  
4 about?

5 **A.** Yes, it is.

6 **Q.** Is it consistent with your understanding of national  
7 prescribing trends in terms of increasing from the '90s up  
8 until sometime in the 2010, 2012 window and then coming back  
9 down?

10 **A.** It is.

11 **Q.** All right. I'd like to show you some documents  
12 relevant to the standard of care issue and the changes in  
13 the standard of care that you talk about in your report.

14 Let me start, if I could, with MC-WV-1135.

15 MR. SCHMIDT: May I approach, Your Honor?

16 THE COURT: Yes.

17 MR. SCHMIDT: Thank you.

18 BY MR. SCHMIDT:

19 **Q.** And just to orient us, this is a publication from  
20 the New England Journal of Medicine. Are you familiar  
21 with that publication?

22 **A.** Yes, I am.

23 **Q.** It's dated January 14, 1982. Can you just characterize  
24 for us the role that the New England Journal of Medicine  
25 plays in the practice of medicine?

1       **A.**    It's, it's one of the most respected medical journals  
2       that there is.

3       **Q.**    And if we look a little further down, there's an  
4       editorial called "The Quality of Mercy." Do you see that?

5       **A.**    I do.

6       **Q.**    Are you familiar -- have you, have you read that  
7       editorial that's actually attached there?

8       **A.**    I have.

9       **Q.**    If we go to Page 3 of the document -- we've skipped the  
10       full journal but just focused on this editorial. It's  
11       written by someone named Marcia Angell. Do you know if she  
12       had a role at the New England Journal of Medicine at this  
13       time?

14       **A.**    Yes. She was a Deputy Editor at the New England  
15       Journal at this time.

16               MR. SCHMIDT: Your Honor, we'd move this document,  
17       MC-WV-1135, into evidence.

18               MR. FARRELL: Judge, this is a medical article,  
19       medical literature, and I don't know that it's appropriate  
20       to admit it into the record as evidence. And to the extent  
21       that it's being offered for notice or some other reason, I  
22       just don't think it's appropriate from the historical  
23       rulings this Court has made about admitting medical  
24       literature.

25               MR. SCHMIDT: Your Honor, just to be --

1 MR. ACKERMAN: Your Honor, may I add --

2 THE COURT: Yes.

3 MR. ACKERMAN: -- to my colleague's statement?

4 To the extent that defendants are relying on 803(18) as  
5 the exception to the hearsay in the document, that exception  
6 does not permit the admission of statements in a learned  
7 treatise, but only permits that a statement in a learned  
8 treatise may be read into evidence but not received as an  
9 exhibit.

10 MR. SCHMIDT: Your Honor, just to orient the  
11 Court, what we're actually moving it in under is 803(16),  
12 16, statements in ancient documents, which I find that  
13 expression a little hurtful. It's a statement in a document  
14 that was prepared before January 1st, 1998, which this was,  
15 and whose authenticity is established. And this is a  
16 self-authenticating document under Rule 902(6).

17 MR. FARRELL: Judge, I vehemently object to the  
18 reference of the year 1998 as being ancient.

19 MR. SCHMIDT: I join.

20 THE COURT: Well, you've got a point, Mr. Farrell.

21 MR. FARRELL: So, in general, Judge, I know this  
22 article. We've talked about this article. I understand the  
23 article. I support the article. I know the New England  
24 Journal of Medicine is a leading text. And I also know the  
25 point Mr. Schmidt is going to make.

1 I'm simply saying that we haven't been admitting  
2 medical learned treatises into the record, but we have  
3 liberally been using them and referencing them with experts  
4 throughout this trial.

5 So I have no problem with referencing it or talking  
6 about it. I'm looking forward to the testimony. I just --  
7 I don't want to start the, the onslaught of admitting  
8 medical literature as learned treatises or antiquities into  
9 the record.

10 MR. SCHMIDT: I think the difference here is the  
11 clear exception in Subsection (16). It's, it's pretty black  
12 and white.

13 THE COURT: Well, --

14 MR. FARRELL: Perhaps, Judge, if it was offered  
15 for the limited purpose of notice or limited purpose,  
16 something other than a learned treatise because if we're  
17 going to start admitting learned treatises, I have a book of  
18 learned treatises and articles that we wish we would have  
19 admitted during our case-in-chief.

20 MR. SCHMIDT: I think if they can come in under  
21 803(16), they could do that. It's a pretty specific rule.

22 THE COURT: It's certainly admissible under  
23 803(18) but it can't be admitted if -- we'd have to have him  
24 read it if we did that.

25 MR. ACKERMAN: And, Your Honor, the part that

1 troubles me, and I will be frank with you that I never  
2 looked into this, is how 803(16) could work to obviate what  
3 appears to be a more applicable exception in 803(18).

4 MR. SCHMIDT: By its language, a statement in a  
5 document that was prepared before January 1st, 1998, and the  
6 authenticity is established.

7 THE COURT: Well, it comes within the literal  
8 reading of (16), doesn't it, Mr. Ackerman?

9 MR. ACKERMAN: I think it does, Your Honor. I  
10 don't dispute that.

11 THE COURT: I'm going to admit it under 803(16) --

12 BY MR. SCHMIDT:

13 Q. So let's --

14 THE COURT: -- for the truth of the matter  
15 asserted.

16 BY MR. SCHMIDT:

17 Q. Let's look at Page 2, please, of this publication,  
18 "The Quality of Mercy." You'll see that up there at the  
19 top. And I just want to read a couple lines to you.

20 It says, "Few things that a doctor does are more  
21 important than relieving pain."

22 Let me pause there. Is that a view you agree with  
23 based on your medical practice?

24 A. Yes, it is.

25 Q. "Yet, the treatment of severe pain in hospitalized

1 patients is regularly and systematically inadequate."

2 Do you see that?

3 **A.** I do.

4 **Q.** And we're back in 1982 at this point in time. Was this  
5 a view that started to be expressed in the medical  
6 literature at this point in time?

7 MR. FARRELL: I'm going to make an objection,  
8 Judge. If we're going to admit this, then we should admit  
9 it for what it is. This isn't medical literature. I  
10 believe this is an editorial.

11 MR. SCHMIDT: I'll rephrase.

12 BY MR. SCHMIDT:

13 **Q.** Is that a view that started to be expressed in the  
14 medical community through various sources at this point  
15 in time, that the treatment of severe pain in  
16 hospitalized patients is regularly and systematically  
17 inadequate?

18 THE COURT: Overruled. I'll let him answer that  
19 question.

20 THE WITNESS: Yes, it is.

21 BY MR. SCHMIDT:

22 **Q.** It goes on to say -- it quotes some data. And then  
23 in the sentence after quoting that data it says, "This  
24 is not for want of tools. It is generally agreed that  
25 most pain, no matter how severe, can be effectively

1 relieved by narcotic analgesics."

2 Do you see that?

3 **A.** I do.

4 **Q.** And, again, are you familiar with the point that there  
5 started to be a movement in the medical profession to do  
6 more to treat pain and recognized opioid analgesics as part  
7 of that?

8 **A.** Yes.

9 **Q.** And, so, where I'm going to go with this --

10 MR. SCHMIDT: And I'm going to pass out the  
11 completed version that we sent last night. We, we have  
12 given counsel a demonstrative we're going to use. We'll  
13 print out a copy, but you should have it from last night.  
14 And we'll give out more when we're done. We're going to  
15 build it with some of these articles.

16 Can we go to that please? I'm just going to track some  
17 of these sources up on a board that we're going to see. And  
18 I'm going to make a confession right at the outset. We had  
19 trouble figuring out our timeline at the bottom.

20 So you'll see there's just years here along the bottom  
21 and it's not to scale. We start with the '80s and then jump  
22 all the way to the '90s and then kind of slow down a little  
23 bit in the '90s.

24 But if you'll bear with me with that, I'm going to put  
25 some of these up on the board.

1           So can we start by putting this article up on the  
2 board?

3 BY MR. SCHMIDT:

4 **Q.** Is that that quote we were just looking at from the  
5 New England Journal of Medicine about, "It is generally  
6 agreed that most pain, no matter how severe, can be  
7 effectively relieved by narcotic analgesics"?

8 **A.** It is, yes.

9 **Q.** All right. Let's go back to the article itself. We'll  
10 come back to this board as we look at other publications and  
11 documents.

12           If we scroll down into the next paragraph, it says,  
13 "One consideration that limits the use of narcotics is the  
14 possibility of a variety of side effects."

15           And then it lists several including drowsiness,  
16 constipation, urinary retention and, most serious,  
17 respiratory depression.

18           "A more important factor is a disproportionate  
19 sometimes irrational fear on the part of the medical  
20 profession and the public alike that patients will become  
21 addicted."

22           Do you see that?

23 **A.** I do.

24 **Q.** And are you familiar with that view being expressed by  
25 doctors at this point in time going forward that there might

1 be a disproportionate, sometimes irrational fear, on the  
2 part of the medical profession and the public that patients  
3 will become addicted?

4 **A.** Yes, that was one of the views that was being put forth  
5 at that time.

6 **Q.** And let me just jump to the end of this article, if I  
7 could, back to the author. I asked you earlier about Marcia  
8 Angell. Is she someone who has standing in the medical  
9 profession?

10 **A.** Yes. Dr. Angell was, was very respected.

11 **Q.** Did she have a reputation one way or another in terms  
12 of her attitude towards drug companies and manufacturers?

13 **A.** Yes. She was well-known as really a fierce critic of  
14 the for-profit pharmaceutical companies.

15 **Q.** Okay. Let's look at some other things that -- if we  
16 could look at that paragraph you pulled up. It states, "It  
17 is instructive to contrast the very low incidence of  
18 important side effects with the very high incidence of  
19 inadequate pain relief. I can't think of any other area of  
20 medicine, in medicine in which such an extravagant concern  
21 for side effects so drastically limits treatment. We are  
22 used to a closer balance between risks and benefits."

23 Do you see that?

24 **A.** I do.

25 **Q.** And can you just comment on that statement,

1 particularly this statement at the end about risk and  
2 benefits?

3 **A.** So Dr. Angell is making the point that we discussed  
4 before that -- which was a point that was made at this time  
5 period that the perception was we're not -- we weren't  
6 treating pain aggressively enough and we were exaggerating  
7 our understanding of the risks.

8 And, therefore, by definition then that would get your  
9 risk benefit calculation off if you accept that argument.

10 **Q.** And then let's just go to the end of, of this article.

11 "Pain is soul destroying. No patient should have to  
12 endure intense pain unnecessarily. The quality of mercy is  
13 essential to the practice of medicine; here, of all places,  
14 it should not be strained."

15 Do you see that?

16 **A.** I do.

17 **Q.** And how does that fit with your experience in pain  
18 treatment and pain management?

19 **A.** I think actually she wrote that very, very well. I  
20 think pain is soul destroying. I think that you wouldn't  
21 want to see a pain -- a patient having to endure intense  
22 pain unnecessarily. And I think that the quality of mercy  
23 is essential to the practice of medicine.

24 **Q.** We've, we've walked through a series of statements in  
25 this editorial. Is it meaningful if an editor at the New

1 England Journal of Medicine makes statements like this to  
2 the medical profession?

3 **A.** Yes. This is a -- the New England Journal of Medicine,  
4 as we've discussed, is one of the most respected medical  
5 journals. Dr. Angell was a very well-known and respected  
6 figure. And, so, a statement like this has a significant  
7 impact on, on physicians.

8 **Q.** I'd like to approach with another document, if I may,  
9 Defense West Virginia 3699. I've given you a copy of a  
10 document entitled Cancer Pain Relief. And below the heading  
11 you see a crest and it says it's from the World Health  
12 Organization in Geneva. Do you see that?

13 **A.** I do.

14 **Q.** And then if we just flip ahead to the third page, it  
15 again repeats the title, Cancer Pain Relief, World Health  
16 Organization, 1986. Are you familiar -- are you familiar  
17 with this document I've just handed you?

18 **A.** Yes, I am.

19 **Q.** Can you comment on the significance of this document in  
20 pain management?

21 **A.** So this document was very, was very significant because  
22 it's the document where the World Health Organization  
23 introduced their cancer pain treatment letter which became  
24 very well-known throughout medicine and, and had a very  
25 significant influence on the practice of treating pain

1 across fields of medicine.

2 MR. SCHMIDT: Your Honor, we move into evidence  
3 Defense West Virginia 3699 under the ancient documents  
4 exception.

5 MR. ACKERMAN: I'd renew our objection, Your  
6 Honor. I would just note that the Advisory Committee Note,  
7 which Ms. Kearse has helpfully provided me, to Rule 803(16)  
8 references letters, records, contracts, maps, and  
9 certificates.

10 So I think -- again, it's our position that the ancient  
11 document exception was not intended to apply to learned  
12 treatises which are referenced in another section.

13 MR. SCHMIDT: The language, just for the record,  
14 that's being referenced is, "Wigmore further states that the  
15 ancient document technique of authentication is universally  
16 conceded to apply to all sorts of documents." And then it  
17 says "including the examples listed."

18 MR. RUBY: And, Your Honor, I know Mr. Schmidt  
19 doesn't need my help, but with respect to Mr. Ackerman's  
20 reference to the term "record," there are definitions, of  
21 course, in the Rules of Evidence.

22 And in Rule 101(b)(4) record is defined to include a  
23 memorandum or report which certainly would include this  
24 document.

25 THE COURT: I'm going to admit it. It's admitted.

1 West Virginia 3699 is admitted.

2 BY MR. SCHMIDT:

3 **Q.** So let's look at what was important about this  
4 document. And I'd like to, again, using the numbers in  
5 the bottom left corner of the page, if we can go to Page  
6 10, please. And there's a heading "Nature of Cancer  
7 Pain." I'm actually going to look at the paragraph  
8 right above that.

9 So now we're up to 1986. This tells us numerous  
10 published reports indicate that cancer pain is often not  
11 treated adequately.

12 Again, is that consistent with some of these  
13 discussions from this time period now up to 1986 about doing  
14 more to treat pain; in this case, cancer pain?

15 **A.** Yes, it is.

16 **Q.** "An analysis of 11 reports covering nearly 2,000  
17 patients in developed countries," and they emphasize that,  
18 "suggests that 50 to 80 percent of patients did not have  
19 satisfactory relief. Many patients with advanced cancer and  
20 moderate to severe pain are not given sufficient analgesic  
21 medication to control their discomfort."

22 Are you familiar with that kind of data from this time  
23 period showing that patients who had cancer pain weren't  
24 given satisfactory relief?

25 **A.** Yes, I am.

1       **Q.** It says, "They are restricted to a weak opioid (e.g.  
2       codeine) or a stronger drug is given on demand instead of  
3       being given at appropriate regular intervals by the clock."

4               Then they talk about developing countries and that data  
5       there.

6               And then the final sentence says, "It seems certain,  
7       however, that most patients do not receive adequate therapy  
8       because of legal and other constraints on access to drugs  
9       and notably to the strong opioids."

10              Do you see that?

11       **A.** I do.

12       **Q.** And, again, was that a sentiment that was being  
13       expressed at this time that legal and other constraints on  
14       prescription opioids were depriving patients of effective  
15       pain relief?

16       **A.** Yes. A constraint such as that and exaggeration of  
17       concerns that we talked about from other, that was on other  
18       documents were leading clinicians to under-use and --  
19       under-use opioid pain medications and to under-treat pain.

20              And, essentially, the argument at that time was that  
21       they -- clinicians were typically getting the risk benefits  
22       wrong and not treating pain aggressively enough, not using  
23       opioid pain medications enough.

24       **Q.** Let's go to Page 50, if we could, of this document. It  
25       says, "Reasons for inadequate control of cancer pain."

1           And if you look at the -- I suppose it's the last  
2 sentence here, it refers to a misconception by doctors,  
3 nurses, and patients to the effect that physical dependence  
4 and psychological dependence are interchangeable terms has  
5 led to the under-use of opioid analgesics."

6           Do you see that?

7       **A.**    I do.

8       **Q.**    Is it meaningful when the World Health Organization is  
9 making a statement like that about under-use of opioid  
10 analgesics?

11      **A.**    Yes, it's very meaningful.

12      **Q.**    Okay. Let's go to the board, if we could, and we'll  
13 just add that quote under use of opioid analgesics, 1986.

14           Why is it meaningful that the World Health  
15 Organization, WHO, is saying what with reference to cancer  
16 pain?

17      **A.**    Because doctors know the World Health Organization.  
18 You would be hard-pressed to find a doctor who doesn't know  
19 the World Health Organization. And when they make a  
20 statement that's that clear saying that we're under-treating  
21 cancer pain and we should use opioids more often, more  
22 aggressively to, frankly, do a better job of treating cancer  
23 pain, that's a, that's a powerful statement coming from an  
24 organization of that stature.

25      **Q.**    Okay. Let's go back to the document. I want to jump

1 ahead now to Page 20.

2 And we see a heading on the side, on the page that says  
3 "Drug Therapy." Do you see that?

4 **A.** I do.

5 **Q.** It says, "The use of analgesic drugs is the mainstay of  
6 cancer pain management."

7 Does that remain true to this day?

8 **A.** That remains true to, to this day, yes.

9 **Q.** It says, "When used correctly, analgesics are effective  
10 in a high percentage of patients. A three-step analgesic  
11 ladder is suggested (see diagram opposite)."

12 And then if we look at Page 21 -- let's just cull up  
13 this diagram that they're referencing.

14 Are you familiar with this diagram?

15 **A.** Yes, I am.

16 **Q.** Have you heard it sometimes referred to as a pain  
17 ladder?

18 **A.** Yes, that's what we commonly refer to it as, the World  
19 Health Organization pain ladder.

20 **Q.** Can you just walk us through -- I see one, two, three  
21 and then references to different types of pain and  
22 treatments. Can you walk us through what this pain ladder  
23 is communicating?

24 **A.** So it's communicating to doctors and other clinicians  
25 that when you encounter a patient with cancer pain, you

1 start with a non-opioid and associated adjuvant medication.  
2 If that gives the patient relief, you are typically going to  
3 stop there. If it doesn't, you go up to the next level, the  
4 next rung.

5 And if pain is persisting or increasing, at that point  
6 it's recommending that you start a weak opioid plus those  
7 non-opioids plus those adjuvant medications. Again, if that  
8 works, you're typically going to stop there.

9 But that if the pain persists or increases, you will  
10 then go up another rung. And now you'll go to strong  
11 opioids, as well as those non-opioid medications and  
12 adjuvants.

13 And you can see at the top that your goal is to achieve  
14 for that patient freedom from cancer pain.

15 **Q.** And picking up on that goal, freedom from cancer pain,  
16 did there come a time where the concepts reflecting this  
17 ladder, stepping up based on the pain and what worked and  
18 didn't work, were applied more broadly in the medical  
19 profession in cancer pain?

20 **A.** Yes. Over time the same -- this had an influence, of  
21 course, on cancer pain. But also it started to have an  
22 influence on treatment of pain including non-cancer pain.

23 **Q.** Okay. Let's go back to the timeline, if we could, and  
24 again recognizing this is horribly not to scale. But in  
25 1995 you put Oxycontin on there.

1           Are you familiar with the FDA's approval of Oxycontin  
2           in 1995?

3           **A.**    Yes, I am.

4           **Q.**    Do you have an understanding as a clinician why it was  
5           approved?

6           **A.**    My understanding it that it was approved in line with  
7           the same approach of trying to have more, more therapies  
8           available, more long-acting opioids available to use to  
9           treat cancer pain and non-cancer pain to give clinicians  
10          more ways to treat pain.

11          **Q.**    Do you have an understanding as to whether during that  
12          broad time period we're talking about, '80s, '90s, as the  
13          medical profession was talking about pain more and opioid  
14          analgesics more, the FDA approved several opioids during  
15          that time interval?

16          **A.**    That is correct.

17          **Q.**    Do you know of any role that distributors play in the  
18          approval of prescription opioids?

19          **A.**    I'm not aware of any role that distributors play in the  
20          approval of opioids.

21                   MR. FARRELL: Judge, if I may, since we're using a  
22          demonstrative, I don't believe the question has been asked  
23          to establish the date or the distinction between approved  
24          and launched or sold.

25          BY MR. SCHMIDT:

1       **Q.**    Do you know when Oxycontin was approved?

2       **A.**    It was approved in 1995.

3               THE COURT:   Does that take care of your objection,  
4   Mr. Farrell?

5               MR. FARRELL:   Sort of.   I also wanted to -- I'll  
6   clean it up on cross.

7               THE COURT:   Okay.   I'll overrule the objection.   I  
8   think, yeah, it's a matter for cross.

9               Go ahead, Mr. Schmidt.

10       BY MR. SCHMIDT:

11       **Q.**    Okay.   I want to ask you about state medical  
12   boards.   Are you familiar with state medical boards?

13       **A.**    Yes, I am.

14       **Q.**    Do they play a role in, when we talk about standard of  
15   care, in setting the standard of care?

16       **A.**    They do.

17       **Q.**    What role do they play?

18       **A.**    So for a doctor to practice, you need your license from  
19   your state medical board.   And if you were practicing  
20   inappropriately, for example, they would be the folks who  
21   could pull your license.

22               So, therefore, as, as a doctor, one tends to pay  
23   attention to what the state medical board is calling for in  
24   terms of appropriate practice.

25       **Q.**    Okay.   Did there come a time where state medical boards

1 began to take steps to support broader opioid prescribing?

2 **A.** Yes, there did.

3 **Q.** As part of your work in this case -- and we've got an  
4 expert coming next week who's going to dive into this more,  
5 so I'm just going to touch this at a very high level.

6 But as part of your work in this case, did you track  
7 whether some of these changes in the standard of care  
8 tracked into guidance documents from the West Virginia Board  
9 of Medicine?

10 **A.** Yes, I did.

11 MR. FARRELL: Judge, I'm going to place an  
12 objection on the record. As indicated in my *voir dire*, this  
13 witness is certainly an expert in the national standard of  
14 care, but is not licensed in West Virginia, does not  
15 practice in West Virginia, and has no basis in fact to make  
16 any comments about the West Virginia Board of Medicine.

17 MR. SCHMIDT: And, Your Honor, I think the fact  
18 that he has general pain management experience, general  
19 opioid experience makes him eminently qualified to look at  
20 West Virginia Board of Medicine documents and comment on  
21 whether they're consistent with --

22 THE COURT: I agree. I think his expertise has  
23 been established to the point where I think he's qualified  
24 to look at the West Virginia materials and pass an opinion  
25 on -- based on those. Overruled.

1 MR. SCHMIDT: And I will be brief with this. May  
2 I approach, Your Honor?

3 THE COURT: Yes.

4 MR. SCHMIDT: Thank you, Your Honor.

5 BY MR. SCHMIDT:

6 **Q.** So just to orient us to what we're looking at,  
7 we've put it up on the screen, MC-WV-01219 which is in  
8 evidence. It's from the State of West Virginia, West  
9 Virginia Board of Medicine. And if we look at the  
10 second page at the end, we see it was adopted by the  
11 West Virginia Board of Medicine in 1997. Do you see  
12 that, Dr. Gilligan?

13 **A.** Yes, I do.

14 MR. ACKERMAN: Your Honor, I just want to note  
15 that the document, while in evidence, was admitted for a  
16 limited purpose, make that clear.

17 MR. SCHMIDT: I don't recall if that's correct or  
18 not. But if that's true, we don't take issue with that. I  
19 didn't have that recollection, but I'm not -- I didn't look  
20 at that.

21 BY MR. SCHMIDT:

22 **Q.** So let's go to the second paragraph of this. It  
23 says, "The purpose of this statement is to clarify the  
24 Board of Medicine's position on the appropriate use of  
25 opioids for patients with chronic non-malignant pain."

1           Let me pause there. What is chronic non-malignant  
2 pain?

3       **A.** So chronic non-malignant pain is chronic non-cancer  
4 pain.

5       **Q.** Okay. "Clarifying those standards show that these  
6 patients will receive quality pain management and so that  
7 their physicians will not fear legal consequences, including  
8 disciplinary action by the board, when they prescribe  
9 opioids in a manner described in this document. It should  
10 be understood that the board recognizes that opioids are  
11 appropriate treatment for chronic non-malignant pain in  
12 selected patients."

13           Do you see that?

14       **A.** I do.

15       **Q.** Is this consistent with this change in national  
16 standards that you've been telling us about at this time in  
17 the 1997 time period?

18       **A.** Yes, it is.

19       **Q.** All right. Let's go two lines -- two paragraphs down.  
20 You talked about the role that state medical boards play in  
21 discipline. Do you remember telling us about that just a  
22 moment ago?

23       **A.** I do.

24       **Q.** It says, "A physician need not fear disciplinary action  
25 by the board if complete documentation of prescribing of

1       opioids in chronic non-malignant non-cancer pain even in  
2       large doses is contained in the medical records."

3             Do you see that?

4       **A.**    I do.

5       **Q.**    And if we can go back to the timeline and put that  
6       quote on the timeline under 1997.

7             Just in general terms, what's the import of a statement  
8       like that from a, from a State Board of Medicine?

9       **A.**    So for a doctor, that's a clear message. It's very  
10       clearly written saying that if you prescribe opioids even in  
11       large doses for non-cancer pain -- and there is a reference  
12       that you're going to have to have complete documentation.  
13       You're going to have to justify your decision to do that in  
14       your medical record which would be for a doctor expected.  
15       That in that case, you need not fear disciplinary action.

16            And that's -- that would typically be quite significant  
17       to a physician because disciplinary action from a medical  
18       board could mean losing your medical license and not being  
19       able to practice medicine, for example.

20       **Q.**    Are you familiar with something called the Federation  
21       of State Medical Boards?

22       **A.**    Yes, I am.

23       **Q.**    Could you tell us what the Federation of State Medical  
24       Boards is?

25       **A.**    So it's a group that tends to write guidelines and

1 documents for -- that are then frequently adopted by medical  
2 boards in the different states.

3 **Q.** Okay. Are you familiar with publications that the  
4 Federation of State Medical Boards has issued over time  
5 regarding prescription opioids?

6 **A.** Yes, I am.

7 MR. SCHMIDT: May I approach, Your Honor?

8 THE COURT: Yes.

9 BY MR. SCHMIDT:

10 **Q.** I've given you what I've marked as Defense West  
11 Virginia 2937. If you look at the top of it -- well,  
12 actually, let's look at the second line -- the third  
13 line, smaller print.

14 Do you see in that sentence there's a reference to the  
15 Federation of State Medical Boards, and it's dated May,  
16 1998. Do you see that?

17 **A.** I do.

18 **Q.** And it says, "Model guidelines for the use of  
19 controlled substances for the treatment of pain."

20 Are you familiar with this document?

21 **A.** Yes, I am.

22 **Q.** At a high level, can you give us an overview of, of  
23 what this document is?

24 **A.** So it's a document written by the Federation of State  
25 Medical Boards spelling out their, their guidelines for the

1 appropriate use of controlled substances to treat pain.

2 And then this is the, the -- this sort of document --  
3 indeed, this one was -- the sort of document that many state  
4 medical boards would then adopt as their, as their  
5 guideline.

6 MR. SCHMIDT: Your Honor, we missed the ancient  
7 records exception by a few months for this document, so I'll  
8 take up Mr. Farrell's invitation to move it in just for the  
9 limited purpose of notice, Defense West Virginia 2937.

10 THE COURT: Is there any objection?

11 MR. FARRELL: No, Your Honor.

12 THE COURT: It's admitted for the limited purpose.

13 BY MR. SCHMIDT:

14 **Q.** Let's look at some of the language in this  
15 document.

16 First of all, if you go to the third paragraph, please,  
17 it states, "The board recognizes that controlled substances,  
18 including opioid analgesics, may be essential in the  
19 treatment of acute pain due to trauma or surgery and chronic  
20 pain whether due to cancer or non-cancer origins."

21 Are you familiar with that statement from the  
22 Federation of State Medical Boards in 1998?

23 **A.** Yes, I am.

24 **Q.** And if we go over to the timeline and put that on a  
25 timeline, 1998, can you comment on the significance, if any,

1 of the Federation of State Medical Boards issuing this  
2 broader statement including the specific recognition that  
3 opioid analgesics may be essential for acute pain due to  
4 trauma or surgery and chronic pain whether due to cancer or  
5 non-cancer?

6 **A.** So it's part of the same change over time and  
7 encouraging increase in the -- essentially increase in the  
8 aggressive treatment of pain with the, the, this concept  
9 that we've been perhaps under-treating pain.

10 And it's significant that they're spelling out not just  
11 acute pain and not just chronic pain due to cancer, but also  
12 including chronic pain due to non-cancer origins.

13 **Q.** And do you understand this to be consistent with the  
14 standard of care regarding prescription opioids as it was  
15 developing in this time period?

16 **A.** Yes, I do.

17 **Q.** Let's go back to the article itself, please, Defense  
18 West Virginia 2937. And if we go back to that third  
19 paragraph, I just want to cull out some other language at  
20 the end.

21 "Physicians should recognize that tolerance and  
22 physical dependence are normal consequences of sustained use  
23 of opioid analgesics and are not synonymous with addiction."

24 Can you explain to us what you understand the  
25 Federation of State Medical Boards to be saying with that

1 statement?

2 **A.** So what they're spelling out for physicians is -- and I  
3 agree with them, by the way -- if, if you prescribe a  
4 significant dose of opioids to any patient over a  
5 significant time period, that patient will become physically  
6 dependent.

7 So if you were to abruptly stop those opioids from one  
8 day to the next, that patient would have a physical  
9 withdrawal and would be sick. But that's not being  
10 addicted. That's just a physical dependence that happens to  
11 everybody. In fact, it happens to every mammal if you give  
12 a significant dose over a significant time.

13 Similarly, the tolerance is that if you give a  
14 significant dose over a significant time, the medication  
15 will have less effect. The patient will become tolerant.  
16 And, again, that's a normal physiologic thing that will  
17 happen to everybody with a sufficient dose over a sufficient  
18 time, whereas addiction is something that's a psychological  
19 phenomenon, compulsive use cravings, that does not happen to  
20 everybody. It happens to a relatively small percentage of  
21 patients. When it does happen, it can be absolutely  
22 devastating, so as to not confuse the patient developing  
23 physical dependence or physical tolerance with a patient  
24 developing addiction.

25 **Q.** And I'd like to go to the next stop on the timeline.

1 Before I do, we've been focusing on some seminal  
2 publications relevant to the standard of care question.

3 Do you have an understanding as to whether there was a  
4 much broader discussion occurring regarding standard of care  
5 that these are leading examples of?

6 **A.** These are examples of the evolution of that standard of  
7 care, but they reflect a broad discussion across pain  
8 medicine, and actually medicine in general, about what's the  
9 appropriate way for us to treat pain and what's the  
10 appropriate way for us to use opioid pain medications to  
11 treat pain.

12 MR. SCHMIDT: May I approach, Your Honor?

13 THE COURT: Yes.

14 BY MR. SCHMIDT:

15 **Q.** I've passed you a document AM-WV-2693. It says  
16 "Joint Commission on Accreditation of Healthcare  
17 Organizations Pain Standards for 2001." Are you  
18 familiar with this document?

19 **A.** Yes, I am.

20 **Q.** Are you familiar with the entity that issued this  
21 document, the Joint Commission on Accreditation of  
22 Healthcare Organizations?

23 **A.** Yes, I am. We, we call it by the acronym JCAHO.

24 **Q.** And what role, if any, do they play in the medical  
25 profession?

1     **A.**     So JCAHO is the body that accredits hospitals and they  
2     accredit other healthcare organizations. And that  
3     accreditation is very important to us to continue to be able  
4     to operate our hospitals. An accredited hospital has  
5     implications for reimbursement, et cetera. So their  
6     accreditation is extremely important to us.

7     **Q.**     And these are, are pain standards for 2001. What, if  
8     anything, is the significance of this accreditation on  
9     issuing pain standards, or any kind of standards for that  
10    matter?

11    **A.**     So the significance of any standards that JCAHO issues  
12    is that they come and inspect us on a regular basis. Often  
13    it's a surprise inspection that you don't know of ahead of  
14    time where they arrive. And they inspect whether we're  
15    meeting their standards for pain treatment or for keeping  
16    the operating rooms sterile, clean enough, or many other  
17    things.

18           And it's very, very important to us to maintain our  
19    accreditation, and very important for us not to have  
20    findings where we're not meeting their standards beyond how  
21    we treat pain or other things.

22    **Q.**     Okay. In terms of these specific pain standards, do  
23    you know whether they are influential in the practice of  
24    medicine?

25    **A.**     Yes, I do.

1 Q. How so -- or how were they if at all?

2 A. So they were influential because they set standards for  
3 measuring pain as the fifth vital sign --

4 Q. Uh-huh.

5 A. -- which was extremely important because if you think  
6 of vital signs, the name, the name says a lot; heart rate,  
7 blood pressure, et cetera, key things. And to then add pain  
8 as a fifth vital sign was a very clear message of how  
9 important JCAHO felt measuring pain and, by implication,  
10 treating pain was and so, therefore, the expectation that  
11 hospitals who are going to be inspected by JCAHO would,  
12 would meet those sort of standards.

13 Q. I'd like to look at what exactly this document says on  
14 that.

15 MR. SCHMIDT: Before I do, we move this document  
16 into evidence for the limited purpose of notice, AM-WV-2693.

17 MR. ACKERMAN: One thing, Your Honor -- we tried  
18 to point this out last night in our objections. It appears  
19 that the back there's a different document that's appended  
20 to it. So you've got ten pages that all appear to be the  
21 same document, and then there's something else.

22 THE COURT: Beginning on page --

23 MR. ACKERMAN: Page 11 at the bottom it looks like  
24 something that is Page 13 of a separate document.

25 MR. SCHMIDT: I think the cover of the document

1 answers that in the second paragraph. It refers to the new  
2 pain standards and some examples are pulled out of the six  
3 chapters in which they appear in these six manuals and are  
4 shown below for your information.

5 So it's, it's an attachment to the original document  
6 that's referenced in the second paragraph on the first page.

7 THE COURT: Yeah. The paragraph on the first page  
8 appears to embrace the parts that you're concerned about,  
9 does it not?

10 MR. ACKERMAN: I think when it says examples are  
11 shown below, it's talking about the content of the document.

12 MR. SCHMIDT: This document has been on the  
13 exhibit list for a long, long time. It's one of the central  
14 documents in the case. I actually moved it into evidence as  
15 an adoptive admission because it's subject to a --

16 THE COURT: I'm going to admit it for the limited  
17 purpose, Mr. Ackerman. You can object -- do you want the  
18 record to show your objection?

19 MR. ACKERMAN: I think it's on the record, Your  
20 Honor.

21 THE COURT: All right. It will do so.

22 BY MR. SCHMIDT:

23 Q. Let's go to Page 12 of this document if we could.  
24 It's the number in the middle this time at the bottom.  
25 And it says "Standard" at the top.

1 And, actually, just before I do, just to make the  
2 record complete, Dr. Gilligan, could you look back with me  
3 at the first page of the document.

4 The second paragraph says, "The new pain standards and  
5 some examples are pulled out of the six chapters in which  
6 they appear in these six manuals and are shown below for  
7 your information."

8 Do you see that?

9 **A.** I do.

10 **Q.** Let's go to Page 11. Remembering those, those words  
11 from the first page about standards and manuals -- I'm  
12 sorry, Page 12, please.

13 You see at the top there's a reference to a manual, the  
14 Comprehensive Accreditation Manual for Hospitals: The  
15 Official Handbook. Do you see that?

16 **A.** I do.

17 **Q.** And then below that there's a reference to "Standard."  
18 Do you see that?

19 **A.** I do.

20 **Q.** The standard is patients have the right to appropriate  
21 assessment and management of pain. Do you see that?

22 **A.** I do.

23 **Q.** And then it looks like the way this document works is  
24 it explains that standard. And it says, "Pain can be a  
25 common part of the patient experience. Unrelieved pain has

1 adverse physical and psychological effects. The patient's  
2 right to pain management is respected and supported. The  
3 healthcare organization plans, supports, and coordinates  
4 activities and resources to assure the pain of all patients  
5 is recognized and addressed appropriately."

6 Do you see that?

7 **A.** I do.

8 **Q.** And what, if anything, is the import of this being part  
9 of an accreditation manual and standard set of that manual  
10 in JCAHO?

11 **A.** So it's of substantial import again because we are  
12 accredited by JCAHO and because it's very, very important to  
13 us to maintain our accreditation, and very important for our  
14 accreditation inspections not to have findings where we're  
15 deficient. So in a set of standards like this, that has a  
16 big effect on, on us running the hospital.

17 **Q.** Let's go back to the page we were looking at, please,  
18 if you could pull that back up, 2693, AM-WV-2693, Page 12.

19 And while we're pulling that up, we can look at our  
20 hard copy documents just in the interest of time.

21 Do you see there's a heading below the standard below  
22 the explanation of the intent of the standard that says  
23 "examples of implementation"? Do you see that?

24 **A.** I do.

25 **Q.** And do you see the references, what you were telling us

1 earlier, it says, "Pain is considered a fifth vital sign in  
2 the hospital's care of patients. Pain intensity ratings are  
3 recorded during the admission assessment along with  
4 temperature, pulse, respiration and blood pressure."

5 Do you see that?

6 **A.** I do.

7 **Q.** And was that a significant consideration in the  
8 standard of care in medicine at this time?

9 **A.** That was a significant consideration again because the,  
10 the other vital signs have been around for -- temperature,  
11 pulse, respiration, blood pressure have been vital signs  
12 that are critical to assessing patients.

13 And, so, to add pain as a fifth vital sign was a very  
14 clear message about the great importance of measuring pain  
15 and, by implication, of treating pain.

16 **Q.** Okay. And you see that as, as Item Number 1 under  
17 examples. And let's just go to the board and put that up on  
18 the board.

19 We're now to 2001. Pain is considered the fifth vital  
20 sign.

21 Can we go back to the second example, AM-WV-2693.  
22 "Every patient is asked a screening question regarding pain  
23 on admission."

24 And then let's just jump down to Number 4. "The  
25 following statement on pain management is posted in all

1 patient care areas (patient rooms, clinic rooms, waiting  
2 rooms, et cetera). Statement on pain management: All  
3 patients have a right to pain relief."

4 Could you comment on the impact of some of these  
5 examples that were given on how to implement this policy in  
6 terms of every patient being asked a screening question  
7 about pain, public postings that we've probably all seen,  
8 all patients have a right to pain relief.

9 **A.** So where every patient is asked a screening question  
10 about pain on admission, then you're getting a measurement  
11 of pain by JCAHO guidance on every patient. And that's  
12 extremely likely to have an effect that you'll now be doing  
13 more to treat patients' pain.

14 If the measurement is very high, the likelihood that  
15 doctors and nurses will then do something to try to treat it  
16 is, I think, a borne out conclusion. And also having the  
17 statement posted in all patient care areas per JCAHO  
18 recommendations, per JCAHO standard setting saying all  
19 patients have a right to pain relief is, is a very clear  
20 statement that if a patient has severe pain, there's a  
21 strong implication that doctors and nurses should, in the  
22 appropriate fashion one would hope, treat, treat their pain.

23 **Q.** Let's go to the next item on the timeline.

24 MR. SCHMIDT: May I approach, Your Honor?

25 THE COURT: Yes.

1 BY MR. SCHMIDT:

2 Q. I've given you MC-WV-1522 which is titled "A Joint  
3 Statement from 21 Health Organizations and the Drug  
4 Enforcement Administration."

5 And then if you look on the right, it appears that it  
6 lists the different organizations. Do you see that?

7 A. I do.

8 Q. And one of them is -- the sixth one down is the  
9 American Medical Association. Do you see that?

10 A. I do.

11 Q. What is the import, if anything, of receiving a  
12 statement from the American Medical Association?

13 A. The American Medical Association is the biggest  
14 organization representing doctors in America. So it's  
15 significant when they're endorsing a statement.

16 Q. If you scroll down, this was in the title, but do you  
17 see the reference to the Drug Enforcement Administration  
18 being listed?

19 A. I do.

20 Q. And it's on the right there, yeah. And then if we go  
21 back to what this joint statement addresses, it states,  
22 "Promoting pain relief and preventing abuse of pain  
23 medications, a critical balancing act."

24 Do you see that?

25 A. I do.

1       **Q.**    Is there -- what significance, if any, does a statement  
2           from the DEA on balancing pain relief and preventing abuse  
3           to pain medications carry?

4       **A.**    So it's significant because the Drug Enforcement  
5           Agency, of course, part of what they're, what they will do  
6           is look at inappropriate use of medications and be an  
7           enforcement agency.

8                So when they're endorsing promoting pain relief while  
9           getting the -- while preventing abuse, that's significant  
10          because the doctor who would be -- might be scared to  
11          prescribe opioids for fear of getting in trouble with  
12          enforcement agencies would take -- would tend to take quite  
13          seriously a message from the Drug Enforcement Agency  
14          endorsing these medications to treat pain in many  
15          situations.

16               MR. SCHMIDT:  I'll move into evidence MC-WV-1522  
17          for the limited purpose of notice.

18               THE COURT:  Any objection?

19               MR. ACKERMAN:  For the limited purpose, no  
20          objection.

21               THE COURT:  Let me make clear it's notice to, to  
22          whom for what?

23               MR. SCHMIDT:  Notice to the medical and healthcare  
24          community regarding the contents --

25               THE COURT:  Regarding the changing standards of

1 the abuse of opioids?

2 MR. SCHMIDT: Yes, Your Honor.

3 MR. FARRELL: I've got an objection to that. I  
4 think it's notice to the defendants, not notice to --  
5 there's no relevance to the notice to the community.

6 MR. SCHMIDT: It's a publication from, among other  
7 sources, the American Medical Association and the branch of  
8 the federal government that regulates all doctors who  
9 prescribe prescription opioids. We're talking about  
10 standard of care. I think it is relevant to notice to  
11 doctors.

12 THE COURT: I think it is too, Mr. Farrell. It  
13 shows the -- it doesn't come in for the truth of the matter  
14 asserted. It comes in to show notice to the medical  
15 profession of the changing standards of the use of opioids.  
16 Isn't that the purpose it's offered, Mr. Schmidt?

17 MR. SCHMIDT: Yes. I think we actually could move  
18 it in as a public record.

19 MR. FARRELL: Okay.

20 THE COURT: I'll admit it for the limited purpose.

21 Do you want to object, Mr. Farrell?

22 MR. FARRELL: No. I guess I'm just a little  
23 confused, but that's okay.

24 BY MR. SCHMIDT:

25 Q. So let's look at what this statement says. If we

1 look -- there's a line, looks like the third paragraph  
2 down, "This consensus statement is necessary based on  
3 the following facts." And then it lists a series of  
4 facts. I'm going to focus on the first two. Do you see  
5 that?

6 **A.** I do.

7 **Q.** The first fact, according to this document, that  
8 necessitates this consensus statement is that, quote,  
9 "Under-treatment of pain is a serious problem in the United  
10 States, including pain among patients with chronic  
11 conditions and those who are critically ill or near death.  
12 Effective pain management is an integral and important part  
13 of the quality of medical care and pain should be treated  
14 aggressively."

15 Do you see that language?

16 **A.** Yes, I do.

17 **Q.** Again, does this reflect the standard of care this time  
18 from the entire American Medical Association and the DEA  
19 about the needs, in the words of this document, to not  
20 simply recognize the problem with under-treatment of pain,  
21 but that pain should be treated aggressively?

22 **A.** Yes, this is part of that changing standard of care.

23 **Q.** Let's look at the next bullet. It says, "For many  
24 patients opioid analgesics, when used as recommended by  
25 established pain management guidelines --" do you see that

1 language?

2 **A.** I do.

3 **Q.** And what do you understand that reference to mean,  
4 established pain management guidelines?

5 **A.** Things like the guidance from the Federation of State  
6 Medical Boards and other similar guidelines.

7 **Q.** "For many patients, opioid analgesics, when used as  
8 recommended, are the most effective way to treat their pain  
9 and often the only treatment option that provides  
10 significant relief." And did I read that correctly?

11 **A.** Yes, you did.

12 **Q.** If we switch over to our board and put that on the  
13 board, is that significant when the DEA and the AMA are  
14 coming out with a statement saying that it's important to  
15 treat pain and they're often the only treatment option that  
16 provides significant relief?

17 **A.** Yes, it's important, again the AMA being the biggest  
18 organization representing doctors in the U.S. and the DEA  
19 being the Drug Enforcement Agency.

20 **Q.** Okay. Can we go back to the original document, please,  
21 MC-WV-1522. And do you still have that in front of you?

22 I think we're having some technical problems. While  
23 we're doing that, I'm going to ask you about one other  
24 paragraph in here. It's the third paragraph in the document  
25 right before that discussion of the consensus statement

1 being necessary based on the following facts.

2 Do you see where it says, "Preventing drug abuse is an  
3 important societal goal but there's consensus by law  
4 enforcement agencies, healthcare practitioners, and patient  
5 advocates alike that that concern should not hinder a  
6 patient's ability to receive the care they need and  
7 deserve."

8 Do you see that language?

9 **A.** I do.

10 **Q.** Do you have an understanding that there was that  
11 consensus described here at this point in time by law  
12 enforcement, by healthcare practitioners, by patient  
13 advocates that concerns about abuse were important, but they  
14 shouldn't hinder a patient's ability to receive the care  
15 they need?

16 **A.** Yes. My understanding is that that was the consensus  
17 view at that time.

18 **Q.** The FSMB continued to issue guidelines over time?

19 **A.** Yes, they did.

20 **Q.** Let's take a look at the next set of guidelines, if I  
21 may just have one second, Your Honor.

22 THE COURT: Yes.

23 MR. SCHMIDT: May I approach?

24 THE COURT: Yes.

25 BY MR. SCHMIDT:

1       **Q.**    I've handed you what I've marked as Defense West  
2       Virginia 3605. And let's put it up on the screen just  
3       in terms of what we're looking at. It says "Model  
4       Policy for the Use of Controlled Substances, Federation  
5       of State Medical Boards." And then there's a reference  
6       to May, 2004. Do you see that?

7       **A.**    I do.

8       **Q.**    Is this an update on those Federation of State Medical  
9       Board standards now from 2004?

10      **A.**    That's correct.

11               MR. SCHMIDT: We'd move this into evidence for the  
12      limited purpose of notice as described before, Your Honor.

13               THE COURT: Any objection?

14               (No Response)

15               THE COURT: Hearing none, it's admitted.

16      BY MR. SCHMIDT:

17      **Q.**    If we look in the second paragraph, it states,  
18      "Since adoption in April 1998 --"

19               Is that a reference to the earlier guidelines we looked  
20      at?

21      **A.**    Yes, it is.

22      **Q.**    "-- the model guidelines for the use of controlled  
23      substances for the treatment of pain have been widely  
24      distributed to state medical boards, medical professional  
25      organizations, other healthcare regulatory boards, patient

1 advocacy groups, pharmaceutical companies, state and federal  
2 regulatory agencies, and practicing physicians and other  
3 healthcare providers. The model guidelines have been  
4 endorsed by the American Academy of Pain Medicine, the Drug  
5 Enforcement Administration, the American Pain Society, and  
6 the National Association of State Controlled Substances  
7 Authorities."

8 Do you have that understanding that their model  
9 guidelines were endorsed by various organizations, including  
10 the DEA?

11 **A.** Yes, that is my understanding.

12 **Q.** Let's go to the next paragraph, please.

13 It states, "Notwithstanding progress to date in  
14 establishing state pain policies recognizing the legitimate  
15 uses of opioid analgesics, there is a significant body of  
16 evidence suggesting that both acute and chronic pain  
17 continue to be under-treated."

18 Do you see that?

19 **A.** I do.

20 **Q.** So just to orient us, we're now in 2004. Are you aware  
21 that prescription levels had actually started increasing by  
22 this point in time?

23 **A.** Yes, I am aware they had.

24 **Q.** Was the Federation of State Medical Boards telling  
25 doctors they could still do more to treat acute and chronic

1 pain?

2 **A.** Yes, I think that's a fair statement of what they're,  
3 of what they're saying.

4 **Q.** Let's go to Page 3. Actually, let's just put that  
5 statement, if we could, up on the board.

6 We're now to 2004. Recognizing that they continued --  
7 let's go back to Defense West Virginia 3605 at the bottom of  
8 Page 2, last sentence, or second to last sentence.

9 It says, "Appropriate pain management is the treating  
10 physician's responsibility. As such, the board will  
11 consider the inappropriate treatment of pain to be a  
12 departure from standards of practice and will investigate  
13 such allegations, recognizing that some types of pain cannot  
14 be completely relieved, and taking into account whether the  
15 treatment is appropriate for the diagnosis."

16 What's the import of the Federation of State Medical  
17 Boards proposing that the medical standard will involve the  
18 board considering inappropriate treatment of pain to be a  
19 departure from standards of practice and will investigate?

20 **A.** So what the Federation of State Medical Boards is  
21 telling doctors there is that if you do not adequately treat  
22 patients' pain, you will have failed to meet the standards  
23 of care, or standard of practice care they use.

24 And, again, where medical boards are the bodies that  
25 grant you your license and can take your license away, a

1 recommendation of that sort from the Federation of State  
2 Medical Boards has a significant influence on doctors.

3 **Q.** Next sentence repeats or says something similar.

4 Can you cull that out, the next sentence on Page 3?

5 "The board recognizes that controlled substances,  
6 including opioid analgesics, may be essential in the  
7 treatment of acute pain due to trauma or surgery and chronic  
8 pain, whether due to cancer or non-cancer origins."

9 Is that a similar statement about the role of  
10 prescription opioids that we saw in the earlier document?

11 **A.** Yes, it's very similar. And, again, it specifically  
12 calls out chronic non-cancer origin in addition to acute  
13 pain and cancer pain.

14 **Q.** Okay. Let's go to the next document on our timeline.  
15 I want to just illustrate whether this tracked through into  
16 West Virginia standards with a document in evidence.

17 MR. SCHMIDT: May I approach, Your Honor?

18 THE COURT: Yes. I don't think you moved 3065  
19 into evidence. Do you want to do that?

20 MR. SCHMIDT: Yes, I would for the limited purpose  
21 of notice, Your Honor.

22 THE COURT: All right. Is there any objection?

23 MR. ACKERMAN: Not for the limited purpose.

24 THE COURT: All right. It's admitted for the  
25 limited purpose.

1 MR. SCHMIDT: Thank you, Your Honor.

2 BY MR. SCHMIDT:

3 Q. So if we put MC-WV-1218 up on the screen, do you  
4 see that this is a West Virginia Board of Medicine  
5 quarterly newsletter from January, 2005?

6 A. I do.

7 Q. And just two quick points on this.

8 If we can scroll down, please, to the first paragraph.

9 Remember in that earlier document there was a reference  
10 to the inappropriate treatment of pain?

11 A. I do.

12 Q. Do you see that defined here in this last sentence for  
13 the purposes of this policy, the inappropriate treatment of  
14 pain includes non-treatment, under-treatment,  
15 over-treatment, and the continued use of ineffective  
16 treatments?

17 A. I, I see that.

18 Q. And then I just want to look down at the bottom of this  
19 page. Do you remember me reading you that language from the  
20 FSMB document about the board will consider the  
21 inappropriate treatment of pain to be a departure from  
22 standards?

23 A. I do.

24 Q. Do you see that same language here adopted by the State  
25 of West Virginia, "The board will consider the inappropriate

1 treatment of pain to be a departure from standards of  
2 practice and will investigate such allegations."

3 Is that guided by the Federation of State Medical  
4 Boards?

5 **A.** That would be my understanding because it's verbatim  
6 from what we saw in the FSMB.

7 **Q.** And if we go to the next page, please, do you see a  
8 similar statement from the West Virginia Board of Medicine  
9 right at the top recognizing that opioids may be essential  
10 in the treatment of acute pain due to trauma or surgery and  
11 chronic pain whether due to cancer or non-cancer?

12 **A.** I see that.

13 **Q.** And let's, let's put that up on the board if we could.

14 The Court has heard evidence about a book by a Dr.  
15 Fishman and I'm not going to -- it's in evidence. The Court  
16 has a copy. I'm not going to spend a lot of time on it. It  
17 was actually mailed to every doctor in West Virginia called  
18 "Responsible Opioid Prescribing." Are you familiar with  
19 that Dr. Fishman book?

20 **A.** Yes, I'm familiar with the book.

21 **Q.** And if we -- let's put up on the screen MC-WV-2111 and  
22 go to Page 15 of the document.

23 I want to just highlight some language the Court has  
24 seen.

25 "Patients should not be denied opioid medications

1 except in light of clear evidence that such medications are  
2 harmful to the patient."

3 Do you see that?

4 **A.** I do.

5 MR. SCHMIDT: Mr. Reynolds, can you put that up on  
6 our board?

7 BY MR. SCHMIDT:

8 **Q.** We're now to 2008 and the corresponding  
9 transmission of this to all doctors in West Virginia.

10 MR. SCHMIDT: And if we go back to the book itself  
11 and cull out that first bullet that was on Page 15. Then  
12 can you also cull out the third bullet. Is it possible to  
13 get both of them together?

14 BY MR. SCHMIDT:

15 **Q.** I read you the first one. The third one says,  
16 "Physicians have a responsibility to minimize the  
17 potential for the abuse and diversion of controlled  
18 substances."

19 Do you see that?

20 **A.** I do.

21 **Q.** Do you understand this book that was sent to every West  
22 Virginia doctor to be in line with standard of care at this  
23 time in terms of when opioids should be prescribed and  
24 having a responsibility to minimize the potential for abuse  
25 and diversion?

1     **A.**    Yes.  I think it was a clear message that on the one  
2     hand doctors should appropriately use opioids to treat  
3     patients' pain, but that also doctors have a responsibility  
4     to think beyond just the patient in front of them to think  
5     about the potential for abuse and diversion of those  
6     medications.

7     **Q.**    Okay.  How do you mesh those two statements?

8     **A.**    I mesh those two in terms of the same sort of balancing  
9     that I think is characteristic in many areas of the practice  
10    of medicine, and certainly in this area of prescribing  
11    opioid medications that you're talking about, you're talking  
12    about significant potential benefits, but you're also  
13    talking about significant potential risks, and that the  
14    doctor is -- as part of his or her job is supposed to think  
15    through those, that risk benefit and weigh it as  
16    appropriately as he or she can with the information  
17    available to them.

18   **Q.**    Two more documents on this timeline if I could.

19           MR. SCHMIDT:  May I approach, Your Honor?

20           THE COURT:  Yes.

21   BY MR. SCHMIDT:

22   **Q.**    And I'll try to do these as quickly as possible.

23           The first document is Defense West Virginia 1944 which  
24    is not in evidence.  The second document is Defense West  
25    Virginia 1935 which is in evidence.

1           My question to you is simply if you -- Defense West  
2           Virginia 1944 is dated --

3           MR. ACKERMAN: Your Honor, --

4           MR. SCHMIDT: -- 2005.

5           MR. ACKERMAN: We have an objection to the use of  
6           Defense West Virginia 1944 because the document did not  
7           appear on the expert's materials considered list.

8           MR. SCHMIDT: It does not. That is correct. It's  
9           substantively identical in terms of what I'm asking him  
10          about to the later version of the document that does.

11          MR. ACKERMAN: Your Honor, I think we went through  
12          this with some of our experts that materials that weren't in  
13          the report you're not allowed to ask about.

14          THE COURT: Well, I'll sustain the objection. You  
15          can use it as a basis to ask him a question if you want to,  
16          Mr. Schmidt.

17          BY MR. SCHMIDT:

18          **Q.** Okay. Let's start with Defense West Virginia 1935,  
19          Page 2. Do you recognize this is from September 9th,  
20          2013, from the State of West Virginia policy on the use  
21          of opioid analgesics?

22          **A.** I do.

23          **Q.** If you look a little further up, do you see that in  
24          this one they're actually clear that they took it from these  
25          Federation of State Medical Board documents we've been

1 talking about?

2 **A.** I see that.

3 **Q.** And in the interest of time, I will go to the third  
4 page of this document. And do you see in the third  
5 paragraph, the first sentence references again the statement  
6 about opioid analgesics are useful and can be essential in  
7 the various range of pain treatments that we've talked  
8 about, acute pain, chronic pain, whether due to cancer or  
9 non-cancer causes?

10 **A.** I see that.

11 **Q.** And if we go to the two paragraphs down, patients  
12 (verbatim) should not fear disciplinary action from the  
13 board for ordering, prescribing, dispensing or administering  
14 controlled substances, including opioid analgesics, for a  
15 legitimate medical purpose in the course of professional  
16 practice when current best clinical practices are met.

17 Do you see that?

18 **A.** I do.

19 **Q.** And then if we look at the next sentence, they define  
20 when use of opioids is for a legitimate medical purpose.  
21 And they say if it's based on sound clinical judgment and  
22 current best clinical practices, is appropriately documented  
23 and is of demonstrable benefit to the patient. Do you see  
24 that?

25 **A.** I do.

1       **Q.**    What's the import of a State Board of Medicine telling  
2       doctors in that state, statements like this about  
3       appropriate use of, of prescription opioids?

4       **A.**    The importance of it is that the State Medical Board is  
5       giving physicians here a fairly clear message that they  
6       would not be -- they shouldn't fear disciplinary action by  
7       the board as long as they practice meeting the standards of  
8       appropriate care. And, so, that they shouldn't let that  
9       fear of potential discipline stop them from using opioid  
10      pain medications in an appropriate fashion.

11      **Q.**    Do you see similar statements -- let's go to the board.  
12      Let's put up the two documents we just used, Defense West  
13      Virginia 1944 from 2010 and Defense West Virginia 1935 from  
14      2013 on the board. Do you see similar statements in between  
15      2005 and 2013?

16      **A.**    I did.

17      **Q.**    Okay.

18               MR. SCHMIDT: Your Honor, may I pass up a copy of  
19      this for demonstrative purposes? Plaintiffs' counsel  
20      already has it.

21               THE COURT: Yes.

22               MR. ACKERMAN: Of what?

23               MR. SCHMIDT: Of the completed time line.

24               MR. ACKERMAN: Oh, okay.

25               MR. SCHMIDT: Thank you.

1 Q. Good afternoon, Dr. Gilligan. I'll pick up where  
2 we left off. We walked through --

3 MR. SCHMIDT: And, and could we just put up the  
4 timeline just to orient us very quickly, McKesson  
5 Demonstrative 11, if that's possible?

6 BY MR. SCHMIDT:

7 Q. So we walked through these various statements from  
8 the national groups, West Virginia Board of Medicine,  
9 took us up until 2013 with the West Virginia Board of  
10 Medicine, repeated a statement about prescription  
11 opioids being essential in certain instances in the  
12 treatment of acute pain and certain types of chronic  
13 pain.

14 Since that time, has the standard of care for  
15 prescription opioids continued to evolve?

16 A. Yes, it has.

17 Q. And, and how has that impacted prescribing rates in the  
18 time period since we were walking through?

19 A. So in the time period since what we walked through, it  
20 has gotten more conservative.

21 Q. Uh-huh.

22 A. And accompanying that, prescribing rates have gone  
23 down.

24 Q. From your perspective, has that been driven by the  
25 medical profession?

1       **A.**    Yes.

2       **Q.**    And if you could characterize the state of prescribing  
3       today, how would you characterize that in terms of  
4       prescription opioids?

5       **A.**    So it's significantly more conservative than the  
6       mind-set in many of the years, or in the years shown there,  
7       certainly many of the years shown there, with more awareness  
8       of the potential ill effects, adverse effects from  
9       medications, risks of the medications for patients, a  
10      greater weighting on that, and also with more skepticism  
11      about the benefits.

12            Again, you know, some patients do well, but a rise in  
13      awareness that many patients won't benefit from them so,  
14      therefore, a shifting of the risk benefit.

15      **Q.**    Okay. Mindful of what you just said, are prescription  
16      opioids still prescribed today for acute pain, just more  
17      narrower perhaps?

18      **A.**    Yes, they are.

19      **Q.**    Are they still prescribed for cancer pain?

20      **A.**    Yes, they are.

21      **Q.**    And, again, mindful of what you told us about the  
22      science on non-cancer chronic pain and what you said just  
23      now, are they still prescribed in certain instances for  
24      non-cancer chronic pain?

25      **A.**    Yes.

1 Q. I'd like to show you a document on some of these points  
2 we've been talking about just now in terms of current  
3 standards.

4 MR. SCHMIDT: May I approach, Your Honor?

5 THE COURT: Yes, you may.

6 BY MR. SCHMIDT:

7 Q. And just to orient us as to what we're looking at,  
8 this is Defense West Virginia 2527. If we look at the  
9 top of the document, we see the AMA logo, the date  
10 June 16th, 2020. And it looks like it's written to the  
11 Chief Medical Officer of the U.S. Centers for Disease  
12 Control and Prevention. Do you see that?

13 A. Yes, I do.

14 Q. Are you familiar with this letter from the AMA?

15 A. Yes, I am.

16 MR. SCHMIDT: Your Honor, we move this into  
17 evidence for the limited purpose of notice.

18 THE COURT: Any objection?

19 MR. FARRELL: Yes, Your Honor. I'm not quite sure  
20 how an expert witness is able to lay the foundation for a  
21 document written by somebody else and sent to a third party  
22 about a subject matter that he was not involved in with the  
23 drafting or writing of this letter. Sure, he can testify to  
24 it all he wants, but this isn't a vehicle to be entering  
25 into the record.

1 THE COURT: Can you lay a little better  
2 foundation, Mr. Schmidt?

3 MR. SCHMIDT: Yeah, yeah, I'll do my best.

4 BY MR. SCHMIDT:

5 Q. First of all, do you understand this to be a  
6 private letter that we somehow obtained or a public  
7 letter?

8 A. I understand it to be a public letter.

9 Q. Do you understand this document to be publicly  
10 available to members of the medical profession?

11 A. Yes, I do.

12 Q. And in terms of -- if we look at the first sentence of  
13 this document, it says it's on behalf of the American  
14 Medical Association and our physicians and medical student  
15 members. Do you see that?

16 A. I do.

17 Q. When the AMA is writing on behalf of themselves and  
18 their physician medical student members, who is that?

19 A. Well, the AMA, as we discussed, is the biggest  
20 association of doctors in the U.S.

21 Q. And after they say that they're writing on behalf of  
22 themselves and the physicians and medical student members,  
23 they say the AMA appreciates the opportunity to --

24 MR. FARRELL: Objection, Your Honor. I didn't  
25 make my first objection just to provide the opportunity to

1 read it into the record.

2 MR. SCHMIDT: I'm trying to lay the foundation as  
3 to what the document is and why --

4 THE COURT: I'm satisfied with the foundation he's  
5 laid so far.

6 Mr. Ackerman.

7 MR. ACKERMAN: Yeah. I am curious as to Mr. -- or  
8 counsel offered the document for purposes of notice. My  
9 question is notice of what to whom?

10 MR. SCHMIDT: Notice of the consensus in the  
11 medical profession to doctors who are being spoken for on --  
12 in this letter and to the healthcare system.

13 THE COURT: I'm going to admit it for the limited  
14 purpose. We need to get through Dr. Gilligan here.

15 MR. SCHMIDT: Okay.

16 THE COURT: Go ahead, Mr. Schmidt.

17 MR. SCHMIDT: Thank you, Your Honor.

18 BY MR. SCHMIDT:

19 **Q.** I'll jump past -- well, actually, just to finish  
20 this sentence, do you see that there's reference --  
21 they're saying they appreciate the opportunity to review  
22 and comment on the Centers for Disease Control and  
23 Prevention guidelines for prescribing opioids for  
24 chronic pain originally published in 2016.

25 **A.** I see that.

1       **Q.**    Do you remember this morning you and I touched on those  
2       CDC guidelines?

3       **A.**    Yes, I do.

4       **Q.**    Could you just remind us of the effect of those CDC  
5       guidelines?

6       **A.**    So the CDC guidelines laid out numerous steps  
7       recommending essentially that doctors should be more  
8       conservative, more cautious in their prescribing of chronic  
9       opioid therapy for non-cancer pain.

10      **Q.**    Okay. Go to Page 3 of the document, please, down at  
11      the bottom. Do you see there's reference to AMA Task  
12      Forces?

13      **A.**    Yes, I do.

14      **Q.**    "The Task Forces further affirm that some patients with  
15      acute or chronic pain can benefit from taking prescription  
16      opioid analgesics at doses that may be greater than  
17      guidelines or thresholds put forward by federal agencies."  
18      And then it lists other bodies. Do you see that?

19      **A.**    I do.

20               MR. FARRELL: Objection, Your Honor. Again, this  
21      is a letter by a third party written to another third party  
22      that's being read into the record by a fourth party. If Dr.  
23      Gilligan wants to testify what he believes to be the  
24      standard of care, we have no objection. He's well  
25      qualified. But neither Deborah Dowell nor James Madara have

1       been called into this courtroom.

2               THE COURT: Mr. Ackerman.

3               MR. ACKERMAN: Yeah. I would add that I don't  
4       think reading this, this sentence is consistent with  
5       admitting the document for a limited purpose. If it's a  
6       limited purpose of notice, that's fine, but --

7               THE COURT: Well, I'll sustain the objection. But  
8       you can ask him the questions without reference to the  
9       document, Mr. Schmidt.

10       BY MR. SCHMIDT:

11       **Q.** Do you, do you --

12               MR. SCHMIDT: Where I was going, Your Honor --

13               THE COURT: If I understand it.

14               MR. SCHMIDT: Yeah. What I was going to ask him  
15       was does he understand this to be the standard of care.

16       BY MR. SCHMIDT:

17       **Q.** So do you understand the standard of care in the  
18       medical profession to reflect that patients with acute  
19       or chronic pain, some patients can benefit from taking  
20       prescription opioids at doses that may still be greater  
21       than guidelines or thresholds set by the Federal  
22       Government or other agencies?

23       **A.** Yes, I do understand that to be the consensus within  
24       the standard of care.

25       **Q.** And last question about this document. If we go to the

1 first page, in the last paragraph on the first page there's  
2 language about the nation no longer having a prescription  
3 opioid-driven epidemic. What we're now facing is a  
4 different --

5 MR. ACKERMAN: Objection.

6 THE COURT: You're doing the same thing that I  
7 sustained the objection to.

8 BY MR. SCHMIDT:

9 Q. Do you have an understanding, sir, as to whether --

10 MR. ACKERMAN: I'd ask that the portion that we  
11 just objected to be taken off the screen.

12 MR. SCHMIDT: It's off the screen.

13 BY MR. SCHMIDT:

14 Q. Do you have an understanding as to whether the  
15 nature of, of drug abuse involving opioid products has  
16 shifted from prescription drugs to illegal heroin and  
17 fentanyl over the past decade?

18 A. Yes, I do.

19 Q. And what, what is that understanding?

20 A. That it has shifted in that way, that it has shifted  
21 from abuse and misuse of prescription opioids to abuse and  
22 misuse of heroin and fentanyl and fentanyl analogues that  
23 are illicit fentanyl, not, not pharmaceutical fentanyl.

24 Q. Just a few questions to round out our, our time  
25 together.

1           As a prescribing physician covering the time period  
2 we've been talking about, including the increase in  
3 prescriptions and then the decrease in prescriptions, do you  
4 have an opinion as a prescribing physician as to which  
5 healthcare decision-makers in the healthcare process drove  
6 those changes in prescribing in both directions?

7       **A.**    Yes, I do.

8       **Q.**    What is that?

9       **A.**    Physicians and other prescribing clinicians.

10      **Q.**    And from your experience, when we were at the peak or  
11 moving up to the peak or coming back down, do you have an  
12 understanding as to whether that prescribing was driven by  
13 good faith medical decisions?

14      **A.**    Yes. I think the great majority of the  
15 over-prescribing was well-intentioned. The majority of  
16 opioid prescribing during much of that period, or perhaps  
17 all of that period was by primary care physicians.

18           And, so, I think there was a great majority of cases of  
19 well-intentioned clinicians trying to follow what they  
20 understood, or in some cases what they had been told, was  
21 the right way to treat patients.

22      **Q.**    Do you have a view as to whether distributors drove  
23 prescribing decisions by doctors in terms of their  
24 understanding of risks and benefits?

25      **A.**    I do.

1 Q. What's that opinion?

2 A. I don't think distributors had an influence on doctors'  
3 prescribing decisions.

4 Q. As someone who's had occasion to prescribe medication  
5 and prescription opioids throughout your career, have you  
6 ever done so based on interactions with a pharmaceutical  
7 distributor?

8 A. No, I have not.

9 Q. In your experience, do distributors -- your experience  
10 in the real world dealing with other doctors, do  
11 distributors play a role that's meaningful in determining  
12 how many prescriptions for opioids or any other product get  
13 written in a given point in time?

14 A. No, they do not.

15 Q. That's all I have, Dr. Gilligan. Thank you.

16 THE COURT: All right. You may cross-examine.

17 CROSS EXAMINATION

18 BY MR. FARRELL:

19 Q. Good afternoon. I introduced myself earlier. I'm  
20 Paul Farrell on behalf of the County Commission and City  
21 of Huntington plaintiffs in this case.

22 I want to take this opportunity to use your expertise  
23 to maybe crystalize or clarify some of the concepts that  
24 we've talked about over the past several weeks.

25 We've inartfully used a phrase of a gateway effect. Is